***United States Court of Appeals***

***for the Second Circuit***

# APPENDIX

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NO. 74-2284 et al.

PAGINATION AS IN ORIGINAL COPY

Nos. 74-2284, 74-2286, 74-2308, 74-2450, 74-2449

JOINT APPENDIX TO THE BRIEFS

VOLUME X

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IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

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THE SOCIETY OF THE PLASTICS INDUSTRY, INC.,

HOOKER CHEMICALS & PLASTICS CORP.,

UNION CARBIDE CORPORATION,

TENNECO CHEMICALS, INC.

and

AIR PRODUCTS AND CHEMICALS, INC.,

Petitioners,

v.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,
UNITED STATES DEPARTMENT OF LABOR;
PETER J. BRENNAN, SECRETARY, DEPARTMENT OF LABOR;
and JOHN H. STENDER, ASSISTANT SECRETARY
FOR OCCUPATIONAL SAFETY AND HEALTH,

Respondents.

UNITED STATES COURT OF APPEALS
FILED
DEC 10 1974
ALANIEL FUSARO, CLERK
SECOND CIRCUIT

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On Petition For Review Of An Order Of
The Occupational Safety and Health Administration,
United States Department of Labor

---

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Products and Chemicals, Inc.

November 12, 1974

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3596



Scavenging System

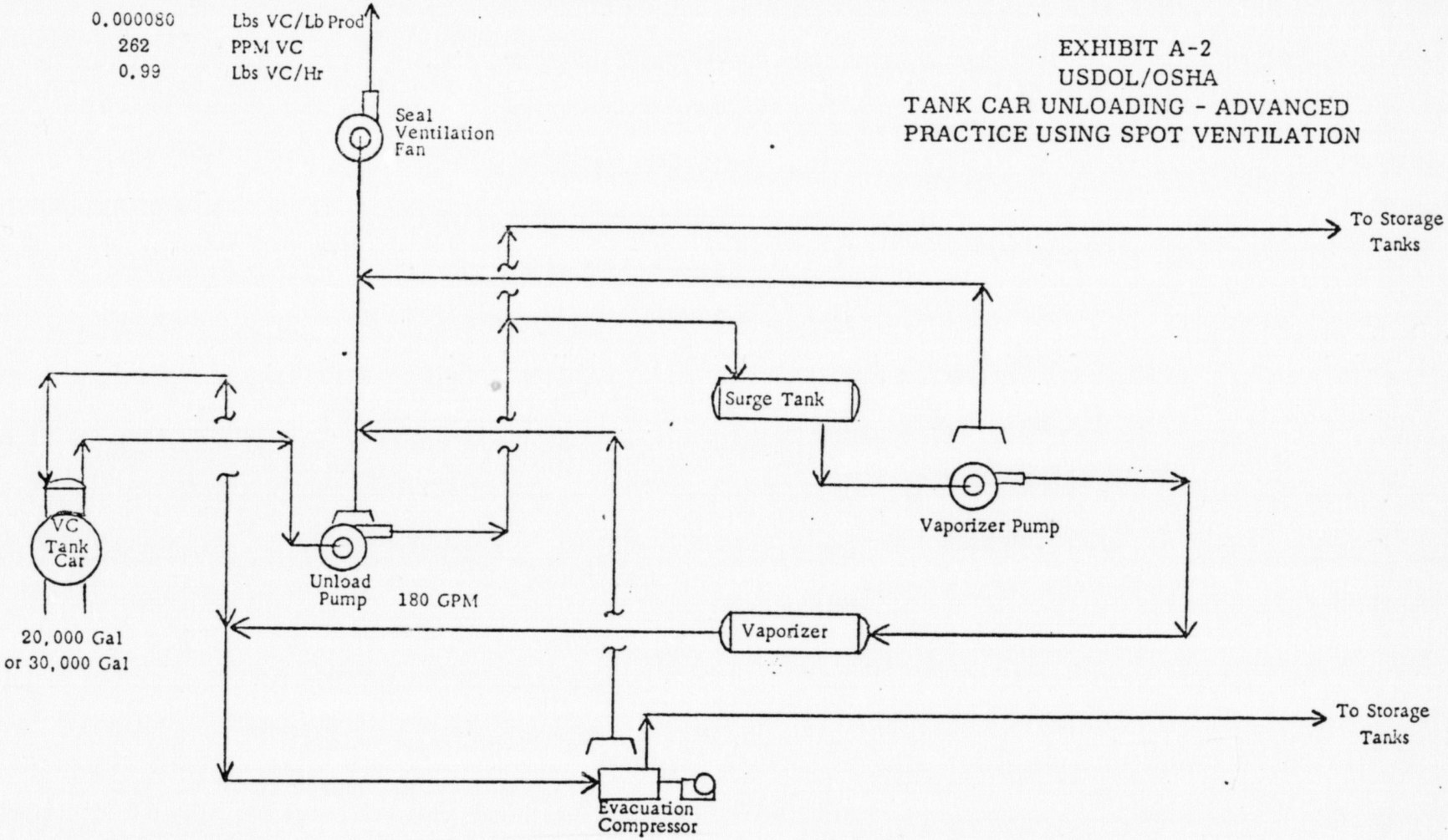
(14) A scavenger compressor system is provided to remove vinyl chloride from lines or hoses which must be disconnected during loading or unloading operations. When scavenging is completed, such lines or hoses are purged with nitrogen to a remote vent stack.

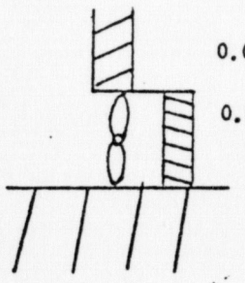
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Source: Testimony of Richard T. Hughes, Vice President, Union Carbide Corporation, before OSHA, on Vinyl Chloride Occupational Exposure Standard, July 5, 1974.

8550

# EXHIBIT A-2
# USDOL/OSHA
# TANK CAR UNLOADING - ADVANCED PRACTICE USING SPOT VENTILATION



Wall Fan (C1002)
0.000066 Lbs VC/Lb Prod
7 PPM VC
0.821 Lbs VC/Hr

BASIS 12,400 LBS/HR PVC

Source: Snell industry interview

3500

EXHIBIT A - 3(1)

USDOL/OSHA

SNELL'S REACTOR DESIGN AND CLEANING OVERVIEW

## 1. REACTOR DESIGN CAN SIGNIFICANTLY REDUCE CHANCES OF EMISSIONS OF VCM

Recent changes have been incorporated to the design of reactors which will contribute in several ways to minimize chances of emission.

### (1) The Trend To Larger Size Reactors Diminishes The Number Of Leakage Points

- In early designs, 1947-1967, the reactors were kettles, usually glass lined, ranging in size from two to five thousand gallons. The bulk of the equipment still in use falls in this category.

- However, new designs have been developed together with manufacturing methods and the most recent equipment incorporates reactors which can be as large as 18,000 gallons if glass lined and even 35,000 gallons (Shinetsu) if stainless. Hüls in Germany is reported to be using a 55,000 gallon reactor.

- Glass lining techniques, transportion restrictions, and heat transfer considerations will limit the size of glass lined equipment to 18,000 gallons.

- The factory cost of an 18,000 gallon glass lined reactor is $350,000, including agitator and drive. The cost of a stainless reactor (clad construction) of 18,000 gallon capacity should be competitive.

- Exhibit A - 4, following this Exhibit, summarizes the advantages and development needs of large reactor technology.

- Design steps such as elimination of the manual charging of minor ingredients, the possible use of ball and plug valves, reduction of the number of flanges can aid in limiting leaks from peripherals.

(2) The Newer Design Bottom Entering Agitators And Baffles Can Significantly Reduce Possible Monomer Leakage

- In the older design, shown in Exhibit A - 5, following Exhibit A - 4, the agitator usually enters the reactor from the top, so that the seal around the shaft is containing the high pressure VCM atmosphere. High Pressure Dual Seal design is used, but since the sealing depends in large part on the oil pressure in the ring, a problem may arise in case of power failure.

- The same problem arises (with lesser severity) with the top entering baffles. Seal deterioration around the baffles has been observed in several instances and creates a particularly insidious problem.

- A newer design, shown in Exhibit A - 6, following Exhibit A - 5, incorporates bottom entering agitator and baffles; thus the seals are containing liquid. It has the double advantage of making the containment easier and to give visual warning of leakages.

- Furthermore, the newer design of the bottom entering seals used in glass lined reactors incorporates a pre-seal in which water at a pressure slightly higher than in the reactor is deliberately allowed to leak in at about 15 g.p.h., thus precluding the possibility of leakage to the outside.

- For the baffle installation, a new flush glass-to-glass seal has been developed; this design could not be used with the conventional nozzle entering baffle.

- In the larger size reactors, baffles are used as an auxiliary cooling surface, adding an extra 25 sq. feet of heat exchange area to an 18,000 gallon reactor.

(3) The Indirect Effects Of Bottom Entering Baffles And Agitator May Be More Important From The Standpoint Of General VCM Levels In The Plant

- The main reason which prompted the design change was the attempt at eliminating, or minimizing, the "Bath Tub Ring" effect.

- This is the formation at the gas liquid interface of agglomerates which cling to the solid surfaces and tend to build up to considerable size, sometimes breaking out in multipound chunks. This phenomenon is particularly bothersome at the comparatively low clearance between baffles and wall. With bottom entering baffles and agitator these effects are virtually eliminated since there is no hydraulic dead space for the agglomerates to form and grow. The reduction or elimination of formation of agglomerates lowers the frequency of strainer cleaning and thus significantly minimizes a source of potential exposure. Pipe clogging is less frequent. Perhaps the main advantage is that the need to open the reactor for inspection and cleaning is greatly reduced.

3563



2. MANUAL REACTOR CLEANING IS A MAJOR CAUSE OF EMISSION PROBLEMS AROUND THE REACTOR

While the most obvious problems associated with manual cleaning of the reactor are the possible emission of VCM upon opening the manhole and the exposure of the man entering the reactor, these do not constitute major engineering difficulties. Adequate venting procedures either are in force or can be implemented to significantly limit exposure to VCM upon opening the manhole. Personal protective devices eliminate the risk of exposure of the man entering the reactor.

But there are two more serious and long-lasting effects of the manual cleaning operation:

- the deterioration of the manhole cover sealing surfaces due to unavoidable chipping from repeated opening and closing
- the possibility that during hand cleaning operation a sight glass may be chipped leading to subsequent bursting under pressure

Several methods have been proposed to reduce or eliminate the need to enter the reactor for cleaning.

(1) Deterioration Of The Manhole Cover Seal Is A Significant Cause Of Leakage

- Every time a manhole is opened in a glass lined reactor, there is a chance for the glass covering the outer part of the manhole nozzle to become chipped.

- In addition, there is a possibility of deterioration of the gasket. A combination of a faulty gasket and a chipped manhole lip is a frequent source of a significant leak. Until recently, little attention was paid to this feature due to the comparatively high ppm level considered acceptable around the reactor.

(2) Design Improvements Have Been Developed To Reduce The Risk Of Deterioration Of The Manhole Cover Seal

- Recently designed glass lined reactors are equipped with an Inconel overlay which is fused to the glass lining in the vertical portion of the nozzle.

- This design eliminates the chances of chipping the glass lining and permits a tighter tongue and groove metal-to-metal seal which, combined with a compressed asbestos gasket, insures a much more durable and positive seal. Unfortunately this design cannot be applied to older reactors unless they are sent to the factory for reglassing. The turnaround time for this can be 60 weeks.

- Replacing the conventional manheads with Lenape's can alleviate leaks around the manhole.

(3) Another Danger Area Is The Rupture Of The Sight Glass

- During manual cleaning it is often necessary to free the nozzles holding sight glasses from accumulated solids. In the process sight glasses may be accidentally chipped, which may induce an undetected hairline crack resulting in a bursting of the sight glass when the reactor is pressurized.

- Another source of sight glass rupture is the removal of the sight glass for cleaning. Upon re-installation, uneven tightening of the bolts is known to have induced stress in the glass with the result that when the pressure stresses were added the sight glass burst. A novel design incorporated in the late models of glass lined reactors eliminates this possibility.

3. IN SITU CLEANING METHODS SHOULD PROVIDE A SOLUTION TO THE LEAKAGES CAUSED BY FREQUENT OPENING OF THE REACTORS

The ideal solution would be to eliminate the need for opening the reactor. Complete in situ cleaning would provide this solution if it could be made thorough enough. Several methods exist or are under development and a brief review of their characteristics is given here.

(1) Historical Changes Have Already Reduced The Frequency Of Cleaning

- In all reactors involving a change from a liquid to a solid phase, such as encountered in PVC production, there is a tendency for the solid to agglomerate and adhere to solid surfaces under certain conditions. This tendency is a function of:

  - nature of the solid and liquid phase(s)
  - quality of the reactor surface
  - presence of stagnant zones in the reactor
  - "Bath Tub Ring" effect

It has been observed that in the course of the development of PVC production from its beginning in the 1940's to the present, two changes have con ributed to reduce the frequency of cleaning:

- a trend to larger reactors has reduced the tendency for the agglomerates to bridge, say between baffles and side

- formula changes seem also to have resulted in a lower tendency for the solids to agglomerate

The result has been that the cleaning frequency has gone down from once every batch to once every four or five batches. Yet this still may constitute an unacceptable frequency.

Furthermore, with the trend to large reactors (10,000 gallons plus), structures had to be erected in the reactor to allow for reaching the required areas (usually in the nozzles on the top cover and at the liquid gas interface). A development was the use of hand directed high pressure (up to 10,000 psi) nozzles. This is in fairly widespread use.

(2) <u>There Are Two Basic Methods For Automatic Cleaning With Some Variants: Water Wash And Solvent Wash</u>

One method uses water under pressure and relies on the mechanical impact of high kinetic energy water particles.

There are two variants of the water method:

- very high pressure low volume spray--a typical instance would be 6,000 psi at 50 g.p.m. for a 5,000 gallon reactor. Cleaning time is twenty minutes

- low pressure high volume spray--typically, for the same 5,000 gallon reactor, 200 psi at 200 g.p.m. Cleaning time is twenty minutes

By and large the problem with water consists simply in separating the solid polymer from the water stream. In fact, for large volume applications, water re-use may be justified.

The other method uses solvents. At present, there are several solvents in use: EDC, Tetrahydrofuran, M-Pyrol, and one as yet undisclosed from Robintech.

The solvent method has two variants:

- in one method the solvent is allowed to completely fill the reactor

- the other solvent method is the use of an automatically controlled solvent spraying

The main drawback of the solvent methods is the need to recover the solvent (they are quite expensive, on the order of $0.50 to $1.00 a pound), and to a certain extent it displaces the problem to the cleaning of the heat exchangers or other solvent recovery devices. This is a major reason for which proprietary rights and patents cover these methods.

(3) The Cleaning Methods Are Proprietary But Are Offered For Licensing

At present there are several methods offered for licensing. Two of them are basically water methods:

GOODRICH HRC
High Pressure Water

- the method involves the use of very high pressure, retractable, multi-directional water sprays; manual cleaning is required approximately after every ten batches
- the equipment cost is about $100,000 (one unit needed per reactor size class); there is a $50,000 usage fee; believed to be non-recurring
- the method drawback is that reactors have to be opened to install the portable equipment, causing deterioration of the manhole cover seal
- the time lag for the institution of this method depends on delays in construction of the specialized equipment, and in acquisition of the ancillary equipment, pumps, tanks, etc. It is estimated at about 6 to 8 months

3569



PFAUDLER Low Pressure Water

- the method involves the use of a patented retractable nozzle assembly which is permanently installed in the reactors. Its advantage is that with twenty minutes of cleaning after each batch, at least twenty-five batches can be processed before another type of cleaning is required. An interesting variant is the use of solvent on, say, every twentieth cleaning. This is claimed to make it unnecessary to enter the reactor for other than annual or semi-annual routine inspection
- the spray nozzle assembly is estimated to cost about $25,000
- ancillary piping and equipment varies widely depending on the number of reactors and such other factors as plant layout, etc. Probably $10,000 per installed reactor is a good approximate figure.
- installation delays may be on the order of 10 to 12 months
- the cost of adding solvent capability may double the capital investment costs

3088



The other proprietary methods involve the use of solvents:

. STAUFFER EDT

- the heart of the method is the solvent recovery unit. A drawback is that it is a soak method in which the reactor is completely filled. Turn around time for a 5,000 gallon reactor is about three hours
- the required equipment involves essentially circulation pumps, solvent storage tank and a solvent recovery unit
- a license fee based on capacity entitles the licensee to flow diagrams, thermodynamics and energy data, operating manuals, etc.
- the cost of the recovery unit is said to vary from $75,000 to $150,000 depending on solvent handling capacity. This does not include the engineering costs nor the storage. For a 5,000 gallons per year of solvent purification a total installed cost of $250,000 to $300,000 appears reasonable
- such an installation may require up to 2 years and significant shut downs of production facilities have to be anticipated
- American Chemical is believed to use the Stauffer method with EDC as the solvent. This may be an interesting solution for integrated plants, where EDC is available

| | | |
|---|---|---|
| GAF Process | - | this process uses a trademarked solvent M-Pyrol and retractable spray devices permanently installed on the reactor. The cleaning devices are installed typically in 4" nozzles. They retract behind a quick opening gate valve during reaction |
| | - | a problem with this equipment is that gate valves are not very reliable as closing devices in presence of solids, so that leakage cannot be ruled out under pressure. The design does not incorporate the elaborate seals required to contain VCM should the gate valve not close completely |
| | - | the costs of equipment are similar to those for the Stauffer process and subject to about the same installation delays |
| SHINETSU Process | - | this is a proprietary process which is an integral part of the Shinetsu Large Reactor Technology. It requires specific design features which may not be economically installed in existing reactors. In addition, the process cannot be used in glass lined reactors. |

Source: Snell Analyses

EXHIBIT A-4(1)

USDOL/OSHA

# COMPARISON OF LARGE REACTOR TECHNOLOGY WITH HISTORICAL REACTOR TECHNOLOGY-AFTER CONOCO

*A new Conoco PVC plant based on the large reactor technology came on stream in 1971 in Oklahoma City, Oklahoma. Conoco also operates a small reactor PVC plant in Aberdeen, Mississippi, and the following data are related to small reactor plants based on our experience at the latter plant. Approximately 32 to 34 small 2200 gallon reactors are needed to provide the same capacity that is obtained in 4 large reactors at Oklahoma City. This means that 8 times as many reactors must be charged, polymerizations contained, stripped, dumped, cleaned, etc. The number of mechanical entities (valves, flanges, pumps, etc.) requiring maintenance (leak problems) is substantially less in the large reactor plant, a strong positive factor in its favor. Moreover, most of the mechanical steps in the new plant are carried out by remote control while the operator keeps all phases under observation by means of charts, schematic diagrams, lights, and closed circuit TV cameras. These comparisons are also based on considerations of the cooling water availability, product mix and the particular chemical and engineering approach in use.*

*Most of the small reactor plants have been constructed with the reactors contained in buildings. Our large reactor plant has only a roof over the reactor building. The associated piping, instrumentation, etc. are enclosed on the sides by a protective metal screen-like structure which covers only about two-thirds of the vertical rise. Therefore, the reactor area is essentially "open air".*

*The large reactor technology, when producing construction type resin, requires personnel entry only about once every thirty days; in small reactors, entry for cleaning is about every 4 or 5 days. Reduced entry frequency is obviously preferred until the goal of zero personnel entry can be achieved by additional research on "clean wall" polymerization formulations. Until that time a combination of solvent cleaning followed by periodic personnel entry in the reactor to manually chip away polymer will be required.*

3513



Our large reactor plant provides about a 98% yield of PVC based on vinyl chloride monomer charged whereas small reactor plant yield is only about 94 to 95%. While the distribution of the yield loss is not fully defined, we believe a significant reduction in atmospheric emissions is being obtained. In addition to the differences in product mix, this difference in yield reflects the fact that fewer operational steps are required in large reactor technology which minimizes the loss of both solid PVC and gaseous VCM. This should provide a workplace with a lower risk for the employee of VCM exposure.

Large reactor manpower requirements are approximately one half that of small reactors on an equal production basis. Two large reactors require two reactormen per shift. Sixteen small reactors, the number necessary to equal the production of two large reactors, require four reactormen per shift. On a per pound basis, large reactors require 0.084 reactormen per million pounds per year while small reactors require 0.168.

In view of what we believe to be positive advantages for large reactor plants, we plan to install additional large reactors to replace the small reactor sections of the Aberdeen plant when appropriate technology is available. At the present time, large reactor technology is limited to a very specific range of resins which find application in the construction industry. These types of resins do not have rigorous requirements on several important PVC properties; e.g. "fisheyes". Although higher quality resins suitable for wire and cable, calendering and other applications have been demonstrated to be technically feasible in our large reactor technology, significant additional developmental effort will be required to demonstrate production of these resins on a commercially practical basis. To accomplish the goal of replacing our small reactors at Aberdeen and of providing resins required by the market, we believe that the following is a very realistic timetable:

..... *Basic R & D Program - 1 year.*

..... *Engineering design and obtaining bids - 1 year*

..... *Plant construction and start up - 3 years*

*This engineering analysis indicates that 5 years are required to implement technology required to satisfy market demands while maintaining our employee VCM exposure in keeping within our proposed standards. In the interim, we plan to meet the proposed standards by restricting work practices (by use of protective equipment, etc.),until such time as we are able to implement the replacement of small reactors with large reactors.*

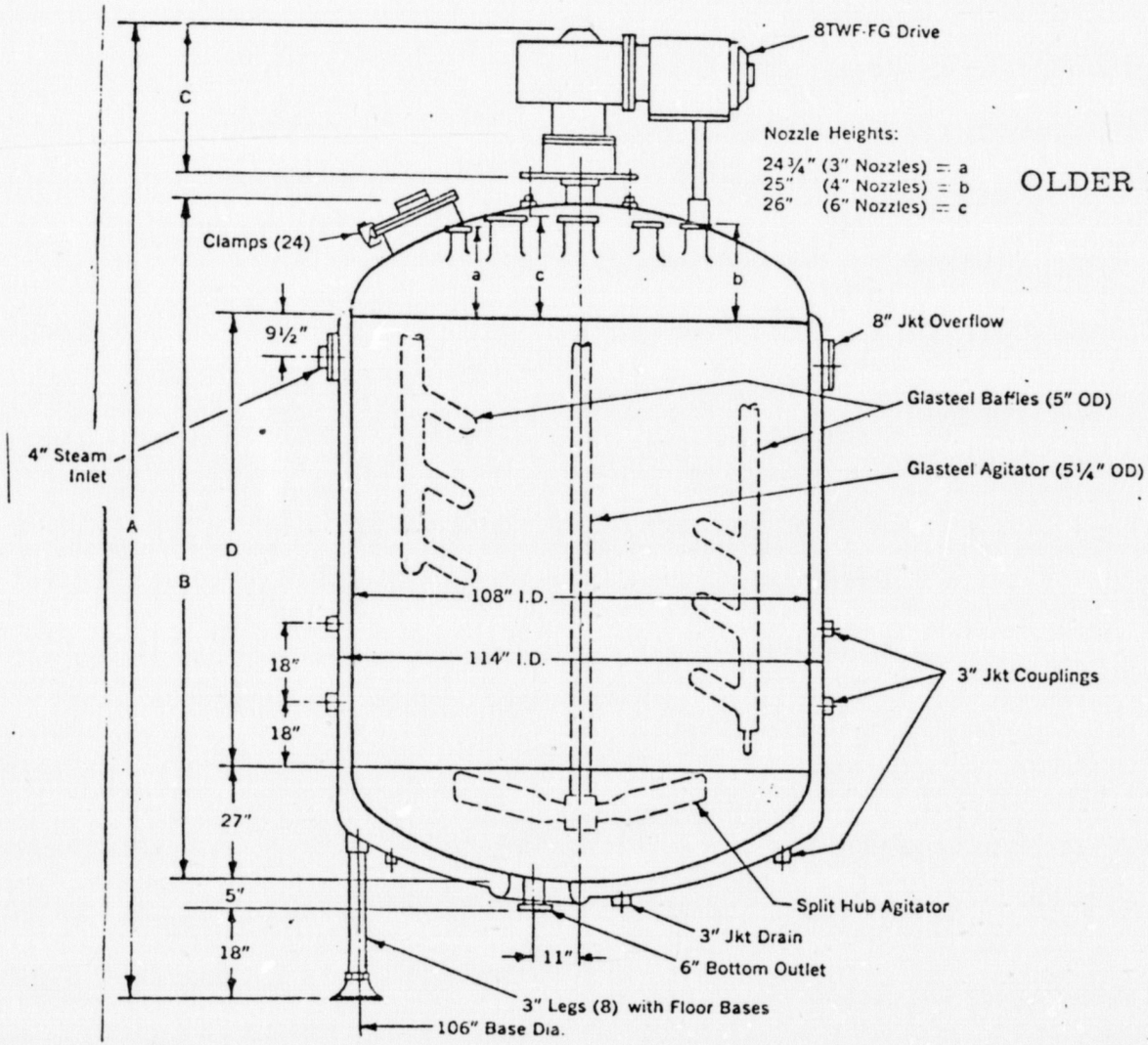
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Source: Submission to Docket Officer, Docket OSH-36, OSHA, by R. W. Genwig, Vice President, Continental Oil Co., June 27, 1974.

EXHIBIT A-5 ..

USDOL/OSHA

OLDER POLYMERIZER DESIGN

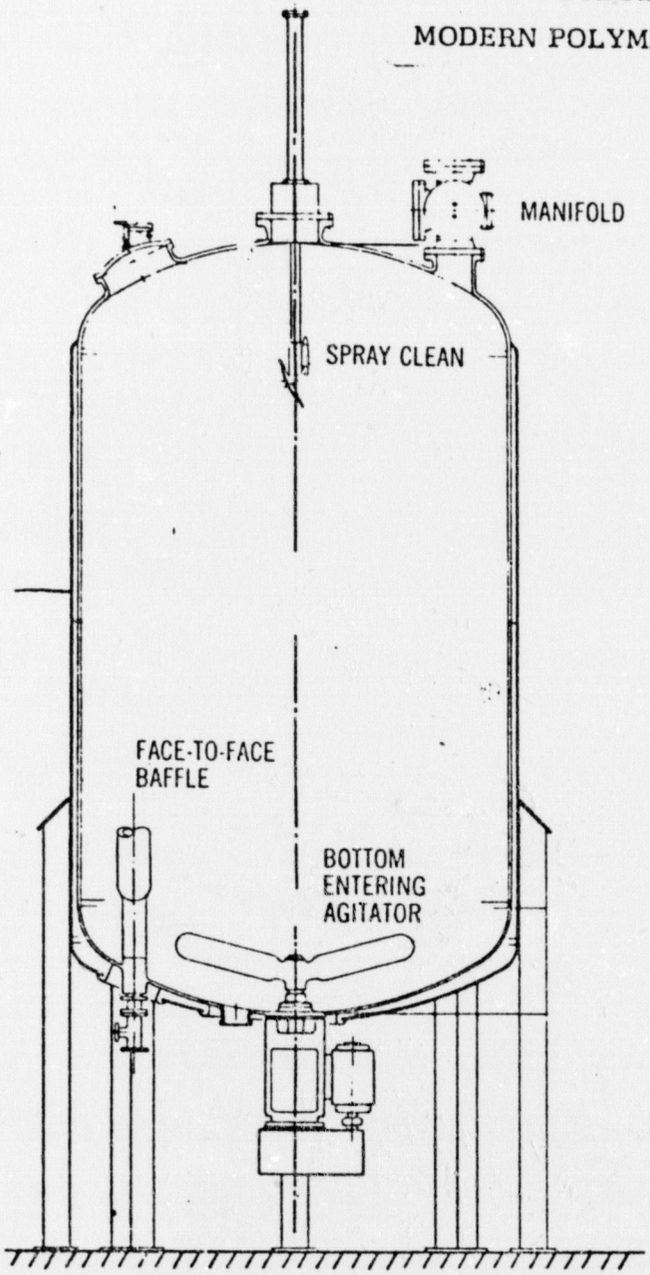



Source: Pfaudler Bulletin 1051, Glasteel Polymerizers

EXHIBIT A - 6 3616

USDOL/OSHA

MODERN POLYMERIZER DESIGN




THE PFAUDLER

GLASTEEL POLYMERIZER

EXHIBIT A-7(1)
USDOL/OSHA

BROAD DISCUSSION OF MONOMER
STRIPPING TECHNOLOGY

## IMPROVEMENTS TO THE STRIPPING STEP IN PVC PRODUCTION WILL MINIMIZE VCM EXPOSURE HAZARD DOWNSTREAM FROM THE REACTORS

Residual VCM in PVC slurry downstream of the reactor causes problems of potential VCM emission through "degassing" of the finished products. Furthermore, there is the possibility of emission in blending and in-process storage, centrifugation, drying and product handling if there is a significant concentration of unreacted VCM in the PVC resin.

Historically, the stripping operation was tailored to minimize VCM losses and thus increase the production yields. A new dimension has been introduced to this operation by the recognition of the hazards which may be created by the existence of significant VCM concentrations in the atmosphere as a result of residual monomer.

Limiting residual monomer in the resin can reduce exposure risk from unit operations downstream of stripping, limit air pollution from dryer exhausts and other downstream sources and limit the exposure risks of compounders and fabricators.

Thus, improvements to the stripping, which are not economically justified by the value of the VCM recovered, have become necessary. This discussion addresses itself broadly to the technology of stripping.

3548



(1) For Economic Reasons The Stripping Method Which Was Found Historically Practical Was The Depressurization Of The Reactors Through A Recovery Unit

A substantial VCM pressure exists at the end of the polymerization cycle. The reactor atmosphere, which is essentially composed of VCM vapors, is vented through a system in which the VCM is cooled and recompressed to a liquid phase which can then be returned to the process. Up to 10-12% of the initial charge can thus be readily returned to the process. However, at atmospheric or near atmospheric pressure a significant concentration of VCM (2 to 3%) remains in the slurry. Slow liberation of VCM occurs when the atmosphere in contact with the slurry is renewed, but the bulk of the free VCM is dissipated during the drying step.

Additional treatment of the slurry via, for instance, reduced pressure, heating, etc., requires both equipment and energy, the costs of which are not justified by the value of the minor amount of VCM thus recovered.

The geometry of the reactor, which is favorable to agitation and heat exchange is not the most favorable for stripping due to a low ratio of free area to liquid volume. This aggravates the foaming problem which is often encountered and requires the use of knockout pots on the recovery lines. Thus, some plants have incorporated an additional vessel in which the stripping takes place. Usually this vessel has about twice the capacity of the reactor and can be of a different geometry (horizontal cylindrical tank) with the liquid level near the center line. This offers not only a better area volume ratio, but also a considerable extra capacity for whatever foam layer is formed. The stripping rate and degree of completion can thus be improved.

(2) An Improvment To The Stripping Which Has Been Implemented In Some Plants Is Pressure Reduction By Steam Jet Or Vacuum Pump

Reduction of the pressure of VCM over the slurry will result in a reduction of VCM concentration in the slurry itself. The advantage of using a vacuum pump is that the discharge of the pump can be handled directly via the recovery system. Steam jet exhaust has to be vented to the atmosphere, thus creating a potential environmental problem.

(3) A Further Refinement Is The Sparging Of Live Steam Into The Slurry, Preferably Under A Reduced Pressure

A further refinement of technology consists in the application of heat to increase the partial pressure of the remaining VCM. This, coupled with reduced pressure over the slurry, should result in a greatly enhanced stripping, bringing the unreacted VCM level in the slurry itself to perhaps 100 ppm. This would have the added advantage of reducing drastically the amount of VCM in the dryer exhaust gas, thus alleviating a potential environmental problem.

(4) More Sophisticated Stripping Methods Are Under Development, But This Work Is Highly Proprietary

As a result of the Emergency Temporary Standard, the industry has been engaged in a vigorous development program addressing itself to the problem of residual monomer in the finished product. In the table below are presented some typical residual monomer concentrations in the major resins since the promulgation of the Emergency Temporary Standard.

| Resin Type | Reported Range of Residual VCM (ppm) | Representative Average (1) (ppm) |
|---|---|---|
| Suspension | 50 - 4,000 | 500 |
| Emulsion | 1 - 400 | 10 |
| Bulk | 0 - 35 | 20 |
| Solution | --- | 1.5 |
| Copolymers | 10 - 14,000 | 1,000 - 7,000 |

(1) Average value considered by industry sources to represent residual VCM levels in common resins of the type indicated. Specialty resins, which represent 10% to 15% of production (generally suspension resins) were reported to contain up to 8,000 ppm.

Source: Industry interviews by Snell

It is seen from the table that considerable reductions are needed in free VCM levels in some resin categories to reach the 100 ppm levels advocated at the OSHA Hearings.

A considerable amount of development work is being carried out, principally addressing itself to the stripping step, to achieve a drastic reduction of residual monomer levels. However, it is reported that for many products increases in the stripping efficiency, e.g., through steam sparging, results in unacceptable deterioration of product characteristics such as, for instance, coagulation of latex. Thus, the development program has also to incorporate changes in the polymerization steps, such as reformulations. The nature and type of the information handled in this development work makes it so confidential that no technical details are publicly available.

Very generally, sophisticated stripping methods such as countercurrent or cascade stripping are said to be under study.

(5) Implementation Time For Stripping Improvements Are Variable

Introduction of vacuum stripping is comparatively easy and will result in immediate improvement in the few remaining plants which do not have this capability. Implementation time of the order of six months is required.

Steam sparging will require more time due to the added requirements of the recovery system which will have to incorporate reflux condensers for the water vapor. From 1.5 to 3 year implementation time can be expected. Time requirements are greatest for those plants which will require additional steam generating capacity.

Stripping of copolymer and latex products to below 100 ppm free monomer levels is reported to require significant technological development.

Newer, more sophisticated methods may already be in the implementation state or, on the other hand, be only at the earliest phase of development. Levels of residual monomer below 100 ppm for all products on a quality controlled continued basis are probably years away.

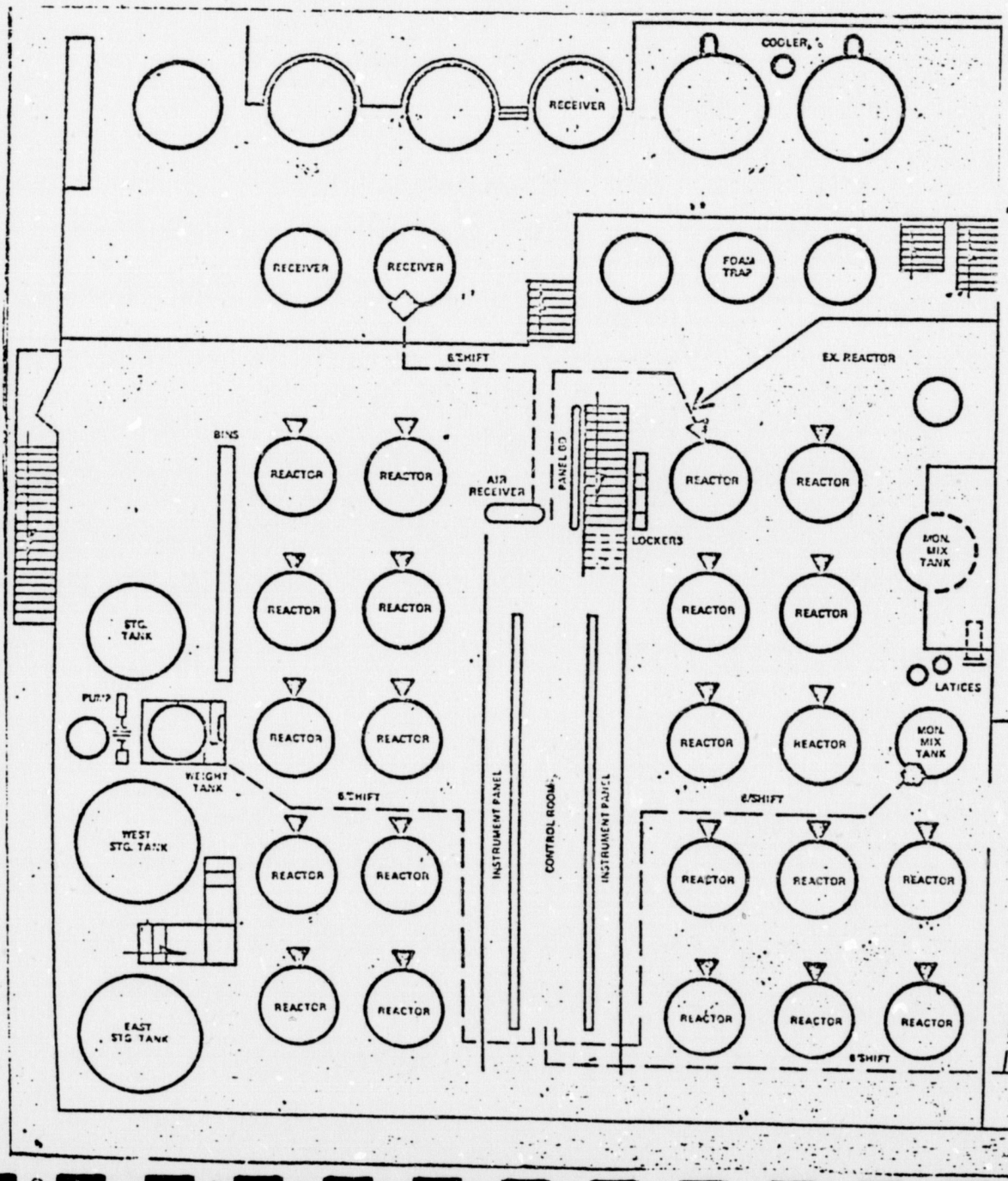
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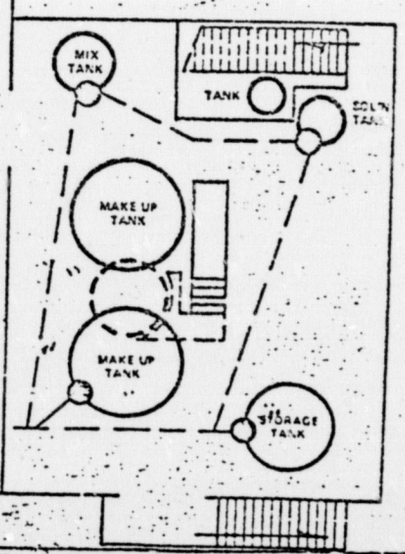
Source: Snell Analysis

EXHIBIT A-8

USDOL/OSHA

# TYPICAL POLYVINYL CHLORIDE OPERATOR MOVEMENTS AND PLANT LAYOUT




▽ TRIPS - CONTROL ROOM TO REACTORS - 80 PER SHIFT

○ MIXING AREA - 6 PER SHIFT

▭ WEIGHT TANK - 6 PER SHIFT

◇ RECEIVER - 6 PER SHIFT

⬡ MON. MIX TANK - 6 PER SHIFT

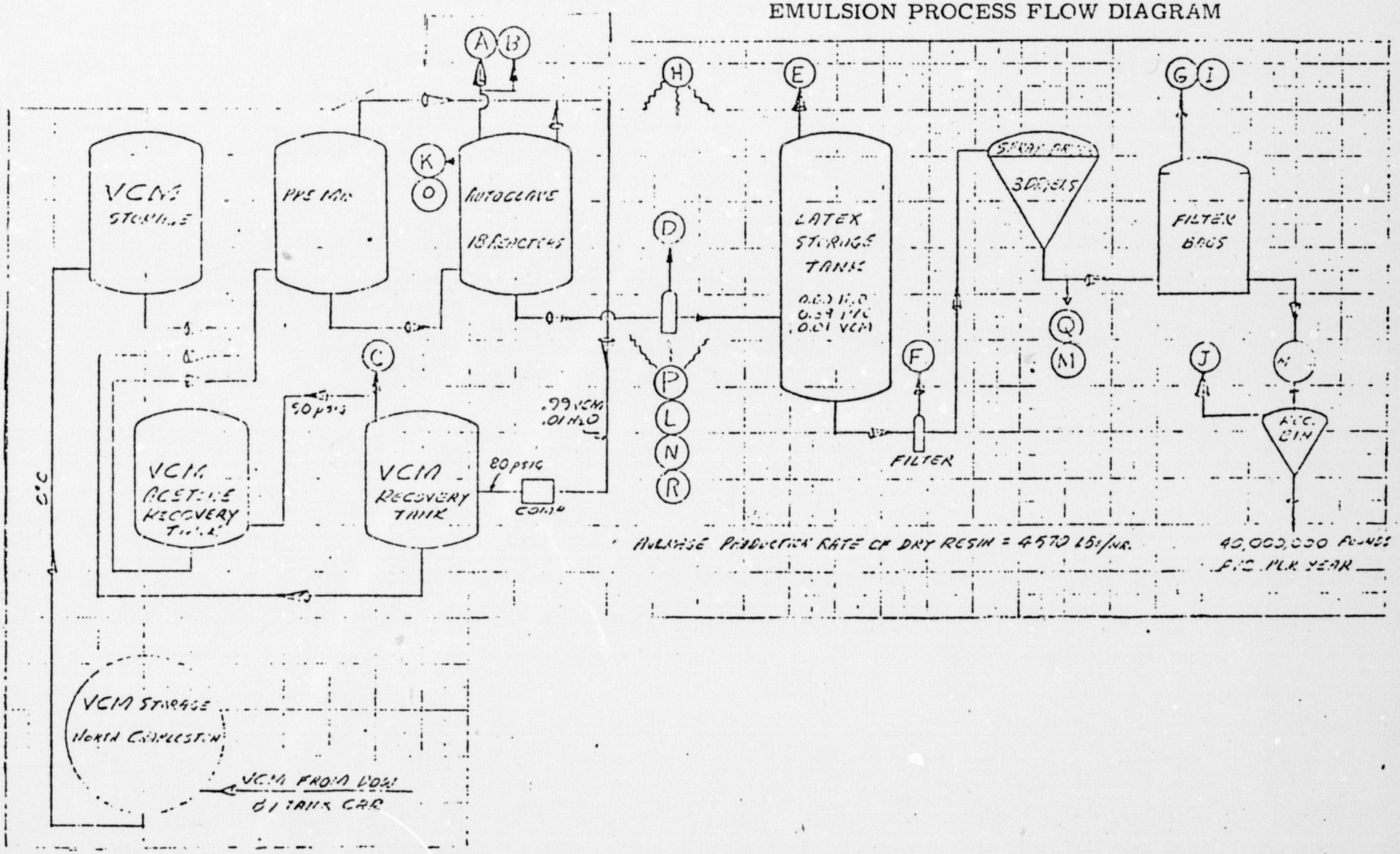
TOTAL DISTANCE PER OPERATOR PER SHIFT
4 - 6 MILES

Source: Industry Interview by Snell

EXHIBIT A-9

USDOL/OSHA

EMULSION PROCESS FLOW DIAGRAM




Source: Industry Interview by Snell.

3524

# APPENDIX B

## EXPOSURE DATA FOR POLYVINYL CHLORIDE (PVC) AND VINYL CHLORIDE MONOMER (VCM) PLANTS

3625

# APPENDIX C

# ECONOMIC DETAILS

3585

# APPENDIX C

## ECONOMIC DETAILS

This appendix presents economic details supporting the findings and conclusions of Chapters IV and V.

- Exhibit C-1 presents typical delivery times for key equipment items.
- Exhibit C-2 presents Snell's overview of the time requirements in implementing engineered controls for VCM exposure in PVC plants.
- Exhibit C-3 is a case study for a PVC plant representative of the industry
- Exhibit C-4 provides the statistical analysis of the economic data for the 50 ppm ceiling case for PVC.
- Exhibit C-5 presents the distribution of reported plant additions of engineering controls estimated for selected VCM levels in PVC plants.

EXHIBIT C - 1(1)

USDOL/OSHA

TYPICAL EQUIPMENT DELIVERY TIMES
FOR MID-1974 ORDERS

| Item | | | Months from Order to Shipment Delivery Time |
|---|---|---|---|
| Pumps[1] | Centrifugals | Carbon Steel (C. S.) | 4 |
| | | Stainless Steel (S. S.) | 6 |
| | | Hastelloy | 14 - 16 |
| | Canned | S. S. to 15 hp | 12 |
| | | 15 to 50 hp | 14 - 18 |
| | Nash Vacuum | 1,000 ACFM 28" Vac. C.S. | 8 |
| | | 1,000 ACFM 28" Vac. S.S. | 18 |
| | Viking (positive displacement) | All sizes | 5 - 6 |
| Valves[1] | All Types | C. S. and S. S. | 4 - 6 |
| | | Other (plastic lined) | 6 - 8 |
| Compressors[2] | Low hp reciprocating | to 10 hp | 2 - 3 |
| | Medium sizes reciprocating | 10 to 100 hp | 4 - 8 |
| | Standard sizes centrifugal | 10 to 100 hp | 4 - 8 |
| | Large sizes centrifugal | over 100 hp | 10 - 12 |
| | Medium sizes screw type | | 4 - 5 |
| Reactor Vessels | Glass lined | 5,000 to 18,000 gal. | 16 - 24 |
| | Stainless | Same sizes | Somewhat less than glass lined |

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| | | | |
|---|---|---|---|
| Tanks | Field erected | over 10,000 gal. | 16 - 20 |
| Spare Parts | Pump shafts, impellers, casing | | 10 - 12 |
| | Valve parts | | 3 - 4 |
| | Agitators for reactors | | 3 - 4 |
| | Gaskets | | 1 - 2 |
| | Filter cartridges | | 1 - 2 |
| | Heat exchanger tubes | C. S. | 9 - 10 |
| | | S. S. | much longer than C. S. |
| | For control instruments | | 2 - 3 |

Notes: (1) 1 to 5 items of standard construction can be obtained straight off the shelf in many instances
(2) Based on delivery schedules reported to be subject to substantial upward revisions

Sources: Interviews with selected major suppliers and Snell estimates

EXHIBIT C-2(1)

USDOL/OSHA
SNELL'S OVERVIEW OF TIME REQUIREMENT
IN IMPLEMENTING ENGINEERED CONTROLS
OF VCM EXPOSURE IN PVC PLANTS

1. THE NATURE OF THE ENGINEERING SOLUTION IS A MAJOR FACTOR IN THE DETERMINATION OF THE IMPLEMENTATION TIME

From Snell's evaluation of the various measures reported by the industry several broad categories of engineering control measures to reduce area VCM concentrations and to forestall excursion have emerged.

- Ventilation, including spot ventilation of critical pieces of equipment
- Modification of the loading/unloading equipment
- Modifications to the reactors including automatic cleaning
- Improvement of the stripping equipment

Others, such as:

- piping modifications
- pump and compressor replacement
- provision for adequate, contained venting of criticial pieces of equipment, sections of piping, etc.

(1) Ventilation Of Enclosed Areas And Spot Ventilation Of Critical Equipment Has Already Been Substantially Implemented To Meet The Emergency Temporary Standard

- While indicating that substantial additions are still required to meet more stringent standards, most of the respondents have installed some form of improved ventilation. In the Northern climates substantial additions to heating equipment will be required to maintain adequate temperatures in the enclosed areas.
- The considerable ductwork and additional heating, necessary to implement the 10 fold increase in ventilation required in many plants, may require up to 6 months of design work, with another 8 months for procurement and 3 months for installation. Thus significant venting improvements have a time delay of about 18 months.
- Comparatively minor work on spot ventilation can usually be accomplished in about 1/2 to 3 months. Necessity for spot welding and such may require a shutdown of at least part of the plant, which, for production reasons, may add a further delay to the implementation.

(2) Changes To The Loading And Unloading Facilities Are Required, Some Of Them May Require Substantial Amounts Of Time

- The replacement of the present system of gauging the tank cars with more sophisticated equipment may be a major cost element to VCM producers who own and operate fleets of tank cars. A delay of 1 year to 2 years may be expected due to the large number of units involved.

- Immediately required changes to loading and unloading facilities pertains to venting of the connect-disconnect line between tank car (or barge) and product storage. This can be accomplished by venting through a vacuum pump, and/or nitrogen flush and implementation is a matter of weeks.

(3) Leaks Around The Reactor May Be The Most Difficult To Control

- The problems of the leaks around the reactors have been fully discussed in Appendix A, and in particular Exhibit A-3.

  - time needed in replacing or reconditioning the reactors is estimated at 18 to 24 months

  - time needed in installing solvent washing system is estimated at 30 months and 24 months for water wash system

(4) Improvement Of Stripping Would Reduce The Amount Of Free Monomer Downstream Of The Reactor, But Implementation May Be Subject To Long Delays

- PVC manufacturers recognize the advantages of improved stripping and some steps have already been implemented in many plants.
- The problem in the implementation of improved stripping systems is that some manufacturers are awaiting the completion of engineering development work before installing any interim improvement.
- A very important element in stripping improvement is the introduction of sparging steam into the stripper. Some plants will have to add steam generating capacity to achieve this, and thus implementation will be dependent on design, procurement and installation of additional steam generating equipment. In this case a delay of up to 3 years can be anticipated.

(5) Implementation Of Other Engineering Control Methods Is More Directly Related To Delays In Equipment Delivery

Typical of such Engineering Control methods would be, for instance:

- Replacement of reciprocating by rotary compressors (estimated delay 18 months).
- Replacement of seal pump by seal-less (canned) pumps (estimated delay 12 months).

- Repiping (substitute welded for flanged).
- Replacement of flexible (or even open channel) transfer lines with permanently connected piping.
- Replacement of open strainers with more sophisticated (possibly self-cleaning) equipment.

2. THE NOVEL TECHNOLOGIES WHICH MAY BE REQUIRED TO ACHIEVE EXTREMELY LOW LEVELS ARE SEVERAL YEARS AWAY.

Due to the extremely proprietary nature of any new development, it is not possible to indicate engineering details of new technologies involved. Continuous polymerization has a good potential, but commercialization has not been achieved to date.

The main areas of new technologies are:

- Radical changes in production methods.
- Generalization of the bulk (or mass) process subsequent to equipment improvements.
- Improvement of stripping.

(1) Radical Changes In Production Methods May Be Under Development

- Continuous polymerization in totally enclosed, remotely controlled trains would obviously contribute to bringing the PVC plant to very low background levels. Appropriate equipment type, with a view to the minimization of leakage, could be incorporated into the design at nominal incremental cost.

The table below summarizes a potential timetable for the implementation of such technology.

Hypothetical Continuous Polymerization Implementation

| Step | Completion Date |
|---|---|
| Develop | January 1976 |
| Demonstrate | January 1977 |
| Design | January 1978 |
| Procure and Install | January 1980 |

A variant may be utilization of part of present equipment. This may lead to a somewhat earlier implementation.

Since such technology is a matter of economics and engineering risk, the added burden of severe limitations on VCM emission may actually help to spur its development by making it more economically attractive. It is to be noted that one respondent indicated the existence of such a technology but described it as "highly uneconomical".

(2) The Bulk (Mass) Process May Potentially Be More Amenable To Low Area Levels Of VCM

- Inherently the bulk process, which has no spent water stream, nor dryer gas to be disposed of, should be more environmentally acceptable. At present too few plants exist in the United States to permit an evaluation of the specific economic impact of engineering controls measures without disclosing proprietary data.

- The values reported by the one respondent using the Bulk Process both for the implementation time and for the costs per pound of capacity are among the highest in the industry.

EXHIBIT C-3
USDOL/OSHA
PVC PLANT CASE STUDY

A CASE STUDY OF A REPRESENTATIVE PVC PLANT DETAILS THE ESTIMATED PROGRESSIVE PLANT ADDITIONS TO REACH A VCM TARGET LEVEL OF 25 PPM CEILING WITH 10 PPM TWA

- Exhibit C-3A details the equipment which the case study plant is installing to meet a 50 ppm VCM ceiling.

- Supplier delays in shipment have delayed installation of ventilation fans and the sequential monitoring system; however, installation of all equipment to reach the 50 ppm VCM ceiling is estimated by the company to be approximately 90% complete.

- Exhibit C-3B details the equipment requirements which the case study plant estimates for a 25 ppm VCM ceiling target level. Engineering, purchase and installation is estimated to require three years.

- Exhibit C-3C details the equipment requirements which the case study plant estimates for a 25 ppm VCM ceiling with a 10 ppm TWA target level. Development, engineering, purchase and installation is estimated to require up to four years.

- Page C-3A(4) presents a sample calculation for productivity loss. In the industry aggregates, productivity loss was calculated based on the plant sample for each VCM target level.

EXHIBIT C-3A (1)

USDOL/OSHA

CASE STUDY, COMPANY ESTIMATED COSTS TO ACHIEVE A 50 PPM VCM CEILING IN A PVC PLANT AND SUSTAIN 1974 CAPACITY

| Item | Description | Capital Costs (¢/lb.) | Annual Costs (¢/lb.) |
|---|---|---|---|
| I. Engineering Controls | | | |
| VCM Unloading | No additions at 50 ppm VCM ceiling | | |
| Ventilation | Building Ventilation | 0.0370 | 0.0033 |
| | Raise Vent Stacks | 0.0014 | 0.0003 |
| | Ventilate Strainer | 0.0028 | - |
| | Supplement Polymerizer Exhaust System | 0.0014 | 0.0007 |
| Reactor Cleaning | Proprietary Equipment | 0.0016 | 0.0007 |
| Stripping | No additions at 50 ppm VCM ceiling | | |
| Other Engineering | Replace Resin Air Conveyor Ducting | 0.0004 | - |
| | New Pump Seals | 0.0004 | - |
| | Housekeeping | 0.0250 | - |
| Subtotal, Engineering Controls | | 0.0700 | 0.0050 |
| Amortization of Capital (12% - 10 Years) | | | 0.0124 |
| Total Annual Engineering Controls Costs | | | 0.0174 |

EXHIBIT C-3A (2)

| Item | | Description | Capital Costs (¢/lb.) | Annual Costs (¢/lb.) |
|---|---|---|---|---|
| II. | Personal Protective Equipment | | | |
| | Showers and Eating Facilities | (Reallocated to 25 ppm VCM ceiling) | | |
| | Breathing | Install Breathing Air Lines | 0.0014 | - |
| | | Respirators and Filters All Employees | 0.0216 | 0.0079 |
| | | Cartridge Respirators | 0.0018 | 0.0659 |
| | | Airfed Respirators | 0.0014 | 0.0026 |
| | Clothing | Daily Coveralls for Employees | - | 0.0528 |
| | | Impervious Suiting | - | 0.0079 |
| | Other | Employee Training | | 0.0082 |
| Subtotal, Personal Protective Equipment | | | 0.0262 | 0.1453 |
| Amortization of Capital (12% - 5 years) | | | | 0.0073 |
| Total Annual Personal Protective Equipment Costs | | | | 0.1526 |

EXHIBIT C-3A (3)

| Item | | Description | Capital Costs (¢/lb.) | Annual Costs (¢/lb.) |
|---|---|---|---|---|
| III. | Monitoring | | | |
| | Personal Monitoring | Pumps, Cartridges and Contract Analysis | 0.0014 | 0.0177 |
| | Area and Leak Monitoring | (3) Organic Vapor Analyzers | 0.0082 | 0.0528 |
| | | Sequential System | 0.0412 | 0.0007 |
| | Medical Testing | Testing Program and Follow-Up | - | 0.0385 |
| | Recordkeeping | Personnel Records | - | 0.0029 |
| Subtotal, Monitoring Costs | | | 0.0508 | 0.1126 |
| Amortization of Capital (12% - 5 years) | | | | 0.0141 |
| Total Annual Monitoring Costs | | | | 0.1267 |
| Subtotal, Engineering, Protective and Monitoring Costs | | | 0.1470 | 0.2966 |
| Productivity Loss[1] | | | 0.84 | 0.46 |
| Total Costs | | | 0.987¢ | 0.7566¢ |

| (1) Productivity Loss | Capital Costs (¢/lb.) | Annual Capital Costs (¢/lb./yr.) | O&M Costs (¢/lb./yr.) | Annual Capital And O&M Costs (¢/lb./yr.) |
|---|---|---|---|---|
| Production Loss = $\frac{\text{No. of Lbs. Lost}}{\text{1974 Capacity (Lbs. - unimpacted by OSHA standard)}} = 0.075$ | | | | |
| Industry Costs Per Lb. of Plant Output (Capital Costs From Exhibit IV-13; Manufacturing Cost From Exhibit IV-13, i.e. Cost of Manufacture Less VCM Costs And Capital Charges) | 11.11¢ | 1.97¢ | 3.90¢ | 5.87¢ |
| Additional Estimated Costs for Engineering Controls in Case Study Plant at 1974 Capacity | 0.07 | 0.01 | 0.00 | 0.01 |
| Subtotal, Estimated Plant Cost Per Lb. Output (Capital Amortized @ 12% - 10 Years) | 11.18 | 1.98 | 3.90 | 5.88 |
| Additional Personal And Monitoring Costs in Case Study Plant at 1974 Capacity (Capital Amortized at 12% - 5 Years) | 0.08 | 0.02 | 0.26 | 0.28 |
| Subtotal | 11.26 | 2.00 | 4.16 | 6.16 |
| Total Additional Costs Per 1974 Production Lb. To Sustain 1974 Production (Capital or Annual Cost x Production Loss) | 0.84¢ | | | 0.46¢ |

Source: Company Interview and Snell estimates.

EXHIBIT C-3B (1)

USDOL/OSHA

CASE STUDY
COMPANY ESTIMATED COSTS TO ACHIEVE A 25 PPM VCM CEILING IN A PVC PLANT AND SUSTAIN 1974 CAPACITY

| Item | Description | Capital Costs (¢/lb.) | Annual Costs (¢/lb.) |
|---|---|---|---|
| I. Engineering Controls | | | |
| VCM Unloading | No additions at 25 ppm VCM ceiling | | |
| Ventilation | Building ventilation | 0.2923 | 0.0264 |
| | Latex blend tank exhaust | 0.0007 | 0.0002 |
| | Exhaust hoods for tanks and charge pumps | 0.0071 | 0.0003 |
| | Vent hoods for recovery pumps | 0.0028 | - |
| | Vent hoods for polymerizers | 0.0082 | 0.0010 |
| | Ventilation for suspension blend tanks | 0.0083 | 0.0010 |
| Reactor Cleaning | Proprietary equipment | 0.0550 | 0.0165 |
| | Modify reactor manhead gaskets to permit multiple reactor opening for cleaning without leakage | 0.0313 | - |
| Stripping | No additions at 25 ppm VCM ceiling | - | - |

EXHIBIT C-3B (2)

| Item | Description | Capital Costs (¢/lb.) | Annual Costs (¢/lb.) |
|---|---|---|---|
| Other Engineering | Proprietary equipment to reduce polymerizer entry | 0.0033 | 0.0016 |
| | Maintenance equipment for pump and line cleaning to reduce employee exposure to VCM (Temporary workplace hoods, exhaust systems, etc.) | 0.0495 | 0.0132 |
| | Strainer bleed-off system to VCM recovery | 0.0220 | - |
| | Reactor cleaning water collection system | 0.0220 | 0.0007 |
| | Replace existing reactor relief system with valves | 0.0769 | 0.0132 |
| Subtotal, Incremental Engineering Controls Costs, 25 ppm VCM Ceiling | | 0.5794 | 0.0741 |
| Engineering Costs To Meet 50 ppm VCM Ceiling | | 0.0700 | 0.0050 |
| Subtotal, Engineering Controls, 25 ppm VCM Ceiling | | 0.6494 | 0.0791 |
| Amortization of Capital (12% - 10 years) | | | 0.1149 |
| Total Annual Engineering Controls Costs, 25 ppm VCM Ceiling | | | 0.1940 |

EXHIBIT C-3B (3)

| Item | Description | Capital Costs (¢/lb.) | Annual Costs (¢/lb.) |
|---|---|---|---|
| II. Personal Protective Equipment | | | |
| Showers and Eating Facilities | Showers and eating facilities | 0.1544 | 0.0609 |
| Breathing | No additions for 25 ppm VCM ceiling | | |
| Clothing | No additions for 25 ppm VCM ceiling | | |
| Other | Training and records | - | 0.0066 |
| Subtotal, Incremental Personal Protective Equipment, 25 ppm VCM Ceiling | | 0.1544 | 0.0675 |
| Personal Protective Equipment Costs To Meet 50 ppm VCM ceiling | | 0.0262 | 0.1453 |
| Subtotal, Personal Protective Equipment Costs, 25 ppm VCM Ceiling | | 0.1806 | 0.2128 |
| Amortization of Capital (Showers and Eating @ 12% - 10 Years, Remaining Items @ 12% - 5 years) | | | 0.0343 |
| Total Annual Personal Protective Equipment Costs, 25 ppm VCM Ceiling | | | 0.2471 |

EXHIBIT C-3B (4)

| Item | Description | Capital Costs (¢/lb.) | Annual Costs (¢/lb.) |
|---|---|---|---|
| III. Monitoring | | | |
| Personnel | Gas Chromatograph (Split 50 - 50 with area monitoring) | 0.0029 | 0.0033 |
| Area and Leak Monitoring | Gas Chromatograph (Split with personnel monitoring) | 0.0029 | 0.0033 |
| Area and Leak Monitoring | Computerize sequential monitoring system for trend analysis | 0.0269 | 0.0020 |
| Medical Testing | No additions for 25 ppm VCM ceiling | - | - |
| Recordkeeping | Included under personal equipment, other | - | - |
| Subtotal, Incremental Monitoring Costs, 25 ppm VCM Ceiling | | 0.0327 | 0.0086 |
| Monitoring Costs To Meet 50 ppm VCM Ceiling | | 0.0508 | 0.1126 |
| Subtotal, Monitoring Costs, 25 ppm VCM Ceiling | | 0.0835 | 0.1212 |
| Amortization of Capital (12% - 5 years) | | | 0.0231 |
| Total Annual Monitoring Costs, 25 ppm VCM Ceiling | | | 0.1443 |
| Subtotal, Engineering, Protective and Monitoring Costs | | 0.91 | 0.41 |
| Productivity Loss (@12.5%) | | 1.50 | 0.81 |
| Total Costs | | 2.41¢ | 1.22¢ |

[redacted]

EXHIBIT C-3C (1)

USDOL/OSHA

CASH STUDY
COMPANY ESTIMATED COSTS TO ACHIEVE A 25 PPM VCM CEILING WITH 10 PPM TWA IN A PVC PLANT AND SUSTAIN 1974 CAPACITY

| Item | Description | Capital Costs (¢/lb.) | Annual Costs (¢/lb.) |
|---|---|---|---|
| I. Engineering Controls | | | |
| VCM Unloading | No additions for 25 ppm VCM ceiling with 10 ppm TWA | - | - |
| Ventilation | No additions for 25 ppm VCM ceiling with 10 ppm TWA | - | - |
| Reactor Cleaning | Clean vessel technology (Includes cleaning techniques and potential reformulation of reactor charge) * | 0.2747 | 0.0275 |
| Stripping | Improved processes to remove VCM from product (Proprietary) * | 5.6044 | 0.0879 |
| Other | Improve reactor emergency relief system (manifold additional values to VCM recovery) | 0.1099 | 0.0055 |
| | Repair VCM leaks | - | 0.0165 |

* Development work is incomplete as of June 1974, company estimates = 4 years to completion.

EXHIBIT C-3C (2)

| | Capital Costs (¢/lb.) | Annual Costs (¢/lb.) |
|---|---|---|
| Subtotal, Incremental Engineering Controls, 25 ppm VCM Ceiling With 10 ppm TWA | 5.9890 | 0.1374 |
| Engineering Costs To Meet a 25 ppm VCM Ceiling | 0.6493 | 0.0791 |
| Subtotal, Engineering Costs,. 25 ppm VCM Ceiling With 10 ppm TWA | 6.6383 | 0.2165 |
| Amortization of Capital (12% - 10 years) | | 1.1750 |
| Total Annual Engineering Controls Costs, 25 ppm VCM Ceiling With 10 ppm TWA | | 1.3915 |

EXHIBIT C-3C (3)

| Item | Description | Capital Costs (¢/lb.) | Annual Costs (¢/lb.) |
|---|---|---|---|
| II. Personal Protective Equipment | | | |
| Showers and Eating Facilities | No additions for a 25 ppm VCM ceiling with 10 ppm TWA | - | - |
| Breathing | | - | - |
| Clothing | | - | - |
| Other | | - | - |
| Subtotal, Incremental Personal Protective Equipment, 25 ppm VCM Ceiling With 10 ppm TWA | | - | - |
| Personal Protective Equipment Costs To Meet a 25 ppm VCM Ceiling | | 0.1806 | 0.2128 |
| Subtotal, Personal Protective Equipment Costs, 25 ppm VCM Ceiling With 10 ppm TWA | | 0.1806 | 0.2128 |
| Amortization of Capital (Showers and Eating Facilities @ 12% - 10 years, Remaining Items @ 12% - 5 years) | | | 0.0343 |
| Total Annual Personal Protective Equipment Costs, 25 ppm VCM Ceiling With 10 ppm TWA | | | 0.2471 |

EXHIBIT C-3C (4)

| Item | Description | Capital Costs (¢/lb.) | Annual Costs (¢/lb.) |
|---|---|---|---|
| III. Monitoring | | | |
| Personal | No additions for 25 ppm VCM ceiling and 10 ppm TWA | - | - |
| Area and Leak | Monitor VCM leaks (Additional Personnel) | - | 0.0082 |
| Medical Testing | No additions for 25 ppm VCM ceiling and 10 ppm TWA | - | - |
| Recordkeeping | No additions for 25 ppm VCM ceiling and 10 ppm TWA | - | - |
| Subtotal, Incremental Monitoring Costs, 25 ppm VCM Ceiling With 10 ppm TWA | | - | 0.0082 |
| Monitoring Costs To Meet a 25 ppm VCM Ceiling | | 0.0835 | 0.1212 |
| Subtotal, Monitoring Costs, 25 ppm VCM With 10 ppm TWA | | 0.0835 | 0.1294 |
| Amortization of Capital (12% - 5 years) | | | 0.0231 |
| Total Annual Monitoring Costs, 25 ppm VCM Ceiling with 10 ppm TWA | | | 0.1525 |
| Subtotal, Engineering, Protective and Monitoring Costs | | 6.90 | 0.56 |
| Productivity Loss (@17.5%) | | 3.15 | 1.34 |
| Total Costs | | 10.05¢ | 1.90¢ |

Source: Company Interview and Snell estimates.

EXHIBIT C-4 (1)
USDOL/OSHA
STATISTICAL ANALYSIS OF THE ECONOMIC DATA
FOR THE 50 PPM CEILING CASE FOR PVC

Snell performed a statistical analysis of the data submitted by the industry and audited by Snell, on the basis explained below.

A unit cost per pound of plant capacity was developed by dividing the total annual costs of compliance by the nameplate capacity for each reporting plant.

Annual cost elements for VCM controls developed by Snell from audit of industry reports as detailed in the case study of Exhibit C-3, the explanatory text of Chapter V, and as summarized below:

- Annual engineering costs including:
  - capital costs at a recovery factor of 12% over 10 years
  - operation and maintenance cost of the additional equipment
  - other costs as reported by the individual plants.
- Annual cost of protective equipment including:
  - capital cost of additional shower and eating facilities over 10 years at 12% capital recovery
  - capital cost of personal protective equipment such as respirators and ancillary equipment amortized over 5 years at 12%
  - costs of short lived items (garments) on a yearly basis
  - operations and maintenance costs of the equipment including the costs of breathing air.

Annual cost of monitoring equipment including:

- capital cost amortized over 5 years at 12%
- operation and maintenance costs of the equipment
- medical and record keeping costs.

The summartion of these cost elements gave, for each plant in the sample, a total annual cost incurred or committed to meet the Emergency Temporary Standard. This total annual cost divided by the nameplate capacity of the plant gives the unit cost per pound of capacity for controlling VCM exposure on an annual basis.

Examination of the data led to the a priori exclusion of three samples from the population. Two are data pertaining to the two Firestone plants and the third sample corresponds to a very small manufacturing plant which has to bear the burden of very high costs on a minimal production (about 1/20 of plant average).

With these exclusions, the characteristics of the population are:

| | |
|---|---|
| Mean unit cost | 0.221¢/lb. |
| Standard Deviation | 0.152 |

The excluded data were examined to validate statistically their exclusion. The differences from the mean were respectively: 2.29¢/lb., 2.076¢/lb., and 0.659¢/lb., 15 Standard Deviation, 13.6 Standard Deviation, and 4.0 Standard Deviation. The highest sample included was only 2.7 Standard Deviations away from the mean. The exclusion of these three samples was statistically justified, particularly given the comparative large size of the sample population examined. In such cases usually an "ascribable cause" for the exclusion is found. As indicated above, in one case the size of the plant was responsible.

EXHIBIT C-4 (3)
USDOL/OSHA

The two other excluded samples represent Firestone data for both plant locations. Snell reviewed the Firestone data with particular care and the audit results are shown in the table below with comparison with the industry averages for ready reference. It can be seen that in all items except monitoring equipment Firestone data are out of proportion with those reported by the rest of the industry.

| Item | | Firestone | | Industry Average |
|---|---|---|---|---|
| | | Pottstown | Perryville | (Other 23 Respondents) |
| Engineering | Capital | $4,[illegible]2[illegible],000 | $1,867,000 | $275,000 |
| Engineering | Annual | 4,271,000 | 2,347,000 | 152,000 |
| Personal Protective Equipment | Capital | 487,000 | 89,000 | 26,000 |
| Personal Protective Equipment | Annual | 135,000 | 37,000 | 38,000 |
| Monitoring Equipment | Annual | 365,000 | 185,000 | 121,000 |

Part of the cost differences which are apparent from the table can be ascribed to inclusion to Firestone of equipment items that the rest of the respondents did not feel necessary to include at the 50 ppm level.

Of particular interest is the inclusion at Pottstown plant of a flare system with a capital cost of 2.5 million dollars and an annual engineering cost (as defined previously) of 2.2 million dollars. This equipment, in Snell's opinion, is not necessary to meet the OSHA requirements and, while it represents an environmental protection device, its inclusion as an answer to a 50 ppm ceiling requirement is not justified. The same can be said for a modification to a waste water treatment system at Perryville at a capital cost of $200,000.

Source: Snell analysis

EXHIBIT C-5 (1)

USDOL/OSHA

DISTRIBUTION OF REPORTED PLANT ADDITIONS OF ENGINEERING CONTROLS ESTIMATED FOR SELECTED VCM LEVELS IN POLYVINYL CHLORIDE PLANTS

| Engineering Item VCM Standard | Number of Plants Not Reporting Detailed Cost Estimates(1) | Number of Plants Reporting Detailed Cost Estimates: Number of Plants Reporting an Initial Expenditure | Number of Plants Reporting an Increased Expenditure | Number of Plants Reporting No Expenditure | Number of Plants Endangered(2) | Approximate Cumulative Capital Cost Per Plant Reporting an Expenditure ($1,000) | Comments |
|---|---|---|---|---|---|---|---|
| VCM Unloading(3) | | | | | | | |
| • 50 ppm ceiling | 2 | 2 | 0 | 17 | 0 | 50 | • Modifications to transport equipment may be completed by VCM supplier. |
| • 25-40 ppm ceiling with 15-25 ppm TWA | 9 | 0 | 0 | 12 | 2 | 50 | |
| • 15-25 ppm ceiling with 10-15 ppm TWA | 7 | 0 | 1 | 8 | 7 | 60 | |
| Ventilation(4) | | | | | | | |
| • 50 ppm ceiling | 4 | 19 | 0 | 2 | 0 | 100 | • Ventilation is used at all levels.<br>• Substantial costs are estimated to reach all target levels.<br>• Most plants have engineered ventilation at the 50 ppm level. |
| • 25-40 ppm ceiling with 15-25 ppm TWA | 9 | 1 | 11 | 1 | 2 | 400 | |
| • 15-25 ppm ceiling with 10-15 ppm TWA | 7 | 1 | 1 | 8 | 7 | 500 | |
| Reactor Cleaning(5) | | | | | | | |
| • 50 ppm ceiling | 4 | 5 | 0 | 14 | 0 | 100 | • 5 of 19 plants install reactor cleaning equipment for the 50 ppm level.<br>• Most plants have reactor cleaning for the 25-40 ppm ceiling with 15-25 ppm TWA target level. |
| • 25-40 ppm ceiling with 15-25 ppm TWA | 9 | 6 | 2 | 4 | 2 | 400 | |
| • 15-25 ppm ceiling with 10-15 ppm TWA | 7 | 0 | 1 | 8 | 7 | - (6) | |
| Stripping(7) | | | | | | | |
| • 50 ppm ceiling | 4 | 6 | 0 | 13 | 0 | 300 | • Three plants report expenditures > $380,000 at the 50 ppm ceiling level probably for new systems.<br>• 7 plants report expenditures of <$70,000 to reach a 25-40 ppm ceiling with 15-25 ppm TWA target level. These expenditures represent improvements to existing equipment. Three plants estimate expenditures >$350,000 probably for new systems.<br>• At the 15-25 ppm ceiling with 10-15 ppm TWA, 7 plants report expenditures > $1 million for R&D and new systems. |
| • 25-40 ppm ceiling with 15-25 ppm TWA | 9 | 7 | 3 | 2 | 2 | 500 | |
| • 15-25 ppm ceiling with 10-15 ppm TWA(8) | 7 | 2 | 6 | 1 | 7 | 4,000 | |
| Other(9) | | | | | | | |
| • 50 ppm ceiling | 4 | 13 | 0 | 6 | 0 | 100 | • Extensive modifications to physical plant are estimated for all levels.<br>• At 15-25 ppm VCM ceiling with 10-15 ppm TWA expenditures of > $400,000 are estimated for such items as emergency reactor pressure relief systems (to VCM recovery) and computerized control systems. |
| • 25-40 ppm ceiling with 15-25 ppm TWA | 9 | 0 | 7 | 5 | 2 | 600 | |
| • 15-25 ppm ceiling with 10-15 ppm TWA | 7 | 2 | 6 | 1 | 7 | 1,200 | |
| Total (10) | | | | | | | |
| • 50 ppm ceiling | | | | | | 650 | |
| • 25-40 ppm ceiling with 15-25 ppm TWA | | | | | | 2,000 | |
| • 15-25 ppm ceiling with 10-15 ppm TWA | | | | | | 5,760 | |

Notes:

(1) Plants in this category did not release detailed cost estimates which could be separated into the five engineering items. Instead a total cost for engineering controls was provided; the total costs per plant for these plants is:

| VCM Target Level | Approximate Cost Per Plant (Dollars in Thousands) |
|---|---|
| 50 ppm ceiling | $ 200 |
| 25 ppm ceiling | 900 |
| 15-25 ppm ceiling | |
| 10-15 ppm TWA' | 3,000 |

(2) Endangered - Management will seriously consider plant shutdown; cost estimates not provided.
(3) Ventilation - Fans, ducting, etc.
(4) VCM unloading - Additions to unloading racks, modifications to VCM piping, unloading pumps and compressors.
(5) Reactor cleaning - High and low pressure water systems and solvent cleaning systems.
(6) Only one plant reported a $500,000 additional expenditure.
(7) Stripping - VCM stripping tanks, pumps, piping, compressors and condensers.
(8) At the 50 ppm and 25 ppm ceiling levels stripping expenditures generally address improvements to present systems to meet in-plant requirements. The much larger expenditures at the 15-25 ppm ceiling and 10-15 ppm TWA levels reflect an effort to also improve the residual free monomer levels in the product.
(9) Other - Non-specific pumps, compressors, piping, seals, etc.
(10) Costs rounded to one significant figure.

Source: Industry interviews and Snell estimates.

# APPENDIX D

## PERSONAL PROTECTIVE EQUIPMENT AND HYGIENE

3055

# APPENDIX D

## PERSONAL PROTECTIVE EQUIPMENT AND HYGIENE

This appendix presents the elements of personal protective equipment and hygiene as related to their purpose, costs, and availabilities. The appendix summarizes the relevant portions of the testimony at the public hearings and details which types of equipment have been purchased by the industry. All exhibits follow the text of the appendix sequentially.

### 1. REVIEW OF THE REGULATORY REQUIREMENTS PRESENTED BY THE OSHA VINYL CHLORIDE TEMPORARY AND PROPOSED PERMANENT EXPOSURE STANDARDS IN RELATION TO PERSONAL PROTECTIVE EQUIPMENT AND HYGIENE ARE SUMMARIZED BELOW

This section summarizes the requirements of employers in the vinyl chloride monomer (VCM) and polyvinyl chloride (PVC) producing industries concerning breathing equipment, protective clothing and personal hygiene as they relate to both the temporary and proposed permanent exposure standards.

#### (1) The Emergency Temporary Standard (ETS) For Exposure To VCM[1]

- The ETS applies to any area or operation in which VCM is:
  - manufactured
  - reacted
  - handled
  - processed
  - released
  - repacked
  - stored

(1) 29 CFR 1910, Occupational Safety and Health Standards Emergency Temporary Standard for Exposure to VCM

- Wherever any monitoring sample reveals VCM at a concentration in excess of 50 ppm, or whenever any accident, such as rupture of equipment or spillage, indicates the likelihood of a greater than usual release of VCM into the ambient air

  - all employees exposed to such concentrations should be withdrawn to a safe area
  - the employees should not be permitted to re-enter the work area unless they wear either
    - type C continuous flow or pressure demand air-supplied respirators
    - self-contained breathing apparatus

- Work which may reasonably be expected to release VCM in concentrations in excess of 50 ppm, such as the

  - repair
  - maintenance
  - cleaning

  of a reactor or other equipment containing VCM, should be accomplished only by employees wearing type C continuous flow or pressure demand air-supplied respirators or self-contained breathing apparatus.

(2) The Proposed Permanent Standard (PPS) For Exposure To VCM[1]

- The PPS states that engineering controls are favored methods of compliance because they tend to avoid contamination of the ambient air in the workplace. However, until these controls are instituted it requires the use of respirators of the continuous flow or pressure demand types only. The PPS requires

(1) 29 CFR 1910 Occupational Safety and Health Standards, Proposed Standard.

- a respiratory protection program in accord with CFR §1910.134 should be established and implemented where respirators are required to be used by the PPS
- respirators should be used only in cases of emergency and where engineering controls or change in work practices have not as yet been instituted
- respirators or combinations of respirators for protection from VCM should be selected from among the following types:
  - .. positive pressure full facepiece self-contained breathing apparatus
  - .. pressure demand full facepiece self-contained breathing apparatus operating in the pressure demand mode
  - .. combination type C pressure demand full facepiece respirator operating in the pressure demand mode and a pressure demand self-contained breathing apparatus operating in the pressure demand mode
  - .. combination type C continuous flow respirator and a pressure demand self-contained breathing apparatus operating in the pressure demand mode

Employee entering regulated areas should be provided with full-body protective clothing, footwear or shoe cover, at no cost to the employee. The employee should be required to wear this clothing. Where PVC powder contains detectable levels of VCM in handling, employee should also be

- provided and required to wear head covering
- required to remove all protective clothing at each exit from the regulated area

- required to shower after the last exit of the day
- clean protective clothing should be provided whenever contaminated or soiled, but not less frequently than weekly
- contaminated clothing should be decontaminated before re-use by removal for laundering or disposal

- Where employees are required by the PPS to wear protective clothing and equipment, change rooms should be provided in accordance with §1910.141(e).
- Where employees are required by this section to shower, shower facilities should be provided in accordance with §1910.141(d)(3).
- The PPS prohibits in regulated areas
  - the storage or consumption of food or beverages
  - the storage or use of smoking or non-food chewing products
  - the storage or application of cosmetics

2. A SUMMARY WAS DEVELOPED OF THE STATEMENTS OF INDUSTRY AND GOVERNMENT REPRESENTATIVES PRESENTING COMPARISONS OF PROTECTIVE EQUIPMENT TYPES AT THE OSHA HEARINGS ON THE PPS

This section presents summaries of selected statements of witnesses at the OSHA public hearings who gave test results on detailed comparisons of respiratory protective devices and protective clothing. These are presented in five exhibits.

- Exhibit D-1 presents the statement of Karl Oelfke, Dow Chemical Company comparing the types of respiratory devices.
- Exhibit D-2 details the presentation of Dr. Joseph F. Tomashefski of the Cleveland Clinic also comparing various types of respiratory equipment.

4. A SUMMARY WAS PREPARED OF SNELL INTERVIEWS WITH VCM AND PVC PRODUCERS TO DETERMINE THE COST OF RESPIRATORY EQUIPMENT AND PROTECTIVE CLOTHING UNDER THE ETS AND THE PROJECTED EXPENDITURES FOR VCM LEVELS BELOW THE ETS

In this section of Appendix D the results of Snell's interviews with the VCM and PVC producing industry in relation to present and projected costs of respiratory equipment and protective clothing are presented. The exhibits detail:

- Purchased equipment and clothing types
- Capital costs
- Operating and maintenance costs (O&M)
- Procurement lead times
- Relevant industry comments regarding topics such as human factors

The information is arranged in the following manner:

- Exhibit D-10 summarizes the costs to the industry for protective equipment under the ETS.
- Exhibit D-11 presents case studies of cost profiles for respiratory equipment as a function of VCM levels and projected covered workers, including expected wearing time.

- Exhibit D-3 is another contribution of Dr. Tomashefski. This exhibit is an in-depth discussion of human factors relating to the use of respirators.

- Exhibit D-4 is a summary of the statement of Dr. Marcus Key, NIOSH, Cincinnati discussing breakthrough times of VCM in air purifying respiratory equipment.

- Exhibit D-5 is a general composite statement of several individuals relating to the human factors involved in wearing protective clothing.

3. BASED ON A SURVEY, SNELL COMPILED RESPIRATORY DEVICES AND PROTECTIVE CLOTHING TYPES INCLUDING DESCRIPTIONS, COMPARISONS, THEIR COST AND AVAILABILITY

This portion of the appendix gives detailed description and comparison of the various types of respiratory devices and protective clothing. Also included are their costs and availability to the industries studied by type and manufacturer. As in the previous section, an exhibit format is used for the presentation of the information.

- Exhibit D-6 is a general presentation detailing the procedure for the selection of the proper type of respiratory protective devices as a function of use.

- Exhibit D-7 is an in-depth of matrix presentation listing respiratory devices and detailing by type important topics including:
  - function
  - advantage
  - disadvantage
  - comparisons with other types
  - Bureau of Mines approval

- Exhibit D-8 presents the costs and availability of typical respiratory devices by type and manufacturer.

- Exhibit D-9 is a comparison to Exhibit D-8 as it describes typical protective clothing types and their cost and availability by manufacturers.

EXHIBIT D - 1

USDOL/OSHA

STATEMENT OF KARL OELFKE
COMPARING TYPES OF RESPIRATORY DEVICES
AT OSHA HEARINGS

| Respiratory Device | Advantages | Disadvantages | Breakthrough Time |
|---|---|---|---|
| Nose-mouth cartridge or canister respirator (N-M) | • Easy to don<br>• Small size<br>• Lightweight<br>• Easy to wear and carry | • Interferes with certain types of eye protection such as goggles<br>• Can't fit all faces | 100 cc canister has breakthrough time of 15 min. at 1 ppm VCM and flow rate of 300 L/min. |
| Full face canister type respirator (FF) w/face mounted canister | • Has larger canister than N-M type last longer<br>• Eye protection is an integral part of mask | • Wearing of hard hat becomes difficult<br>• Can't fit all faces | Acme canister of 300 cc size had breakthrough time to 1 ppm of 23 min. at 1000 ppm VCM. |
| Full face canister type w/chest mounted canister | • Longer breakthrough time than above | • Bulkiness<br>• Can't fit all faces<br>• Poor mobility for worker due to air hose | 1 ppm breakthrough after 167 min. Same conditions as above. |
| Continuous flow air supplied hood (Acid Hood) | • Good head spill protection | • Bulkiness<br>• Vision restriction<br>• Lack of head movement<br>• Poor mobility for worker | (NA) |
| Continuous flow air supplied hood (Acid Hood) | • Good protection | • Vision restriction<br>• Poor mobility for worker due to air hose | (NA) |
| Continuous flow air supplied full mask | • Best of air supplied breathing apparatus | • Wearing of hard hat becomes difficult<br>• Poor mobility for worker due to air hose | (NA) |
| Self-contained breathing apparatus | • Mobility | • Air supply is normally limited to 15-20 minutes in the pressure demand mode | (NA) |
| Portable breathing air cylinders | • Mobility<br>• Long respiratory protection. Two hours at a demand of 53 L/min. | | (NA) |

Source: Karl Oelfke, Production Manager for Vinyl Chloride, Texas Div., Dow Chemical Co., Statement presented to USDOL/OSHA Hearings on Vinyl Chloride; Occupational Exposure Standard, June 25, 1974 and Snell assessment.

EXHIBIT D-2

USDOL/OSHA

STATEMENT OF DR. JOSEPH F. TOMASHEFSKI COMPARING TYPES OF RESPIRATORY EQUIPMENT AT OSHA HEARINGS

| Respiratory Device | Purpose | Method of Operation | Advantages | Disadvantages | General Comments |
|---|---|---|---|---|---|
| 1. Air Purifying Type | Used to remove contaminants from an atmosphere that contains an adequate concentration of $0_2$ (>16% by volume). | Work by either filtration, adsorption, or a chemical reaction to remove contaminants. | Canister masks have attached to them a canister containing an adsorbent. Such masks are of value in protection against:<br>. Organic vapors<br>. Acids<br>. Ammonia<br>. Carbon dioxide<br><br>They are very effective and they can provide effective and reliable protection. | Respirators intended to filter particulates offer no protection against gases or vapors.<br><br>Air purifying respirators produce high resistance to breathing. Adequate fit to the face contour because of differences in size and shape and anthropological characteristics is often a problem. Many times masks must be molded to individuals--as a result leakage commonly occurs.<br><br>The resistance to both inspiration and expiration causes most workers to discard filter type masks especially if they can't see the dust; yet this time, non-visible dust may be most harmful.<br><br>Chemical cartridge type masks are usually of the half mask variety, the chemical adsorbents (charcoal, soda lime, or silica gel) have very limited application and are of value when used against vapors and gases of low toxicity. | To prevent clogging of the canister and to decrease the resistance to breathing it is permissable to remove the filter within such units where protection against particulates is not required. |
| 2. Air-supplied | Usually employed for specific tasks or for hazardous environments. | This type has a hose connected to an uncontaminated air source. They may be equipped w/wo blowers or they may have an airline attachment for continuous or demand flow. | They may be used with full face masks, hoods, or with full body suits. Many air-supplied respirators employ a slight positive pressure in order to prevent inward leaks. They are good for hazardous environments not immediately dangerous to life. | When blowers are employed with such respirators, it is necessary to have an individual attending the blower or a stand-by. Such respirators produce an increased resistance to breathing. They frequently have a long hose attached, which, in itself, may be a nuisance or a safety hazard.<br><br>There are limitations on the maximum length of hose that can be used:<br>. Use w/o blower: < 50 ft.<br>. Use w/blower: 150 ft. to 200 ft. | One must be sure that compressed air supplied is free of CO and $CO_2$. |
| 3. Self-Contained | Provide complete respiratory protection for any concentration of toxic gas or oxygen deficiency. | Pressure-demand type. The slight negative pressure initiated by the individual at the beginning of inspiration triggers the valve so that the gas will flow as it is needed at an appropriate rate. | They can be used with an air source or an oxygen source. | The self-contained apparatus is heavy, bulky and requires highly trained individuals for use. | It is necessary when one employs self-contained respirators to have warning devices indicating that the pressure supply is getting low. |

Source: Joseph F. Tomashefski, M.D., Head of Pulmonary Disease Department of The Cleveland Clinic, statement presented to USDOL/OSHA hearings on vinyl chloride; Occupational Exposure Standard, June 25, 1974 and Shell assessment.

EXHIBIT D-3 (1)

USDOL/OSHA

STATEMENT OF DR. JOSEPH F. TOMASHEFSKI
DISCUSSING HUMAN FACTORS IN RESPIRATOR USE AT
THE OSHA HEARINGS - PROPOSED PERMANENT STANDARD

## GENERAL PROBLEMS ASSOCIATED WITH RESPIRATOR USE

| Problem Areas | Problems |
|---|---|
| 1. Safety in Terms of Fit and Improper Sealing of Mask | • If a leak occurs at the mask, especially an inward leak, the toxic materials may be inhaled and a false security will be provided.<br>• There is a marked variability in the contour of faces--therefore it is very important that any mask fit comfortably, otherwise an individual using it over a long period of time may find a mask to be intolerable. |
| 2. Perspiration | • When effort is expended and work is performed requiring increased oxygen demand, perspiration is not adequately evaporated--it remains within the mask and produces an unpleasant effect.<br>• Toxic substance may become trapped between the skin and the mask causing local irritation.<br>• Allergic reactions have been known to occur. |
| 3. Psychological | • Many people find the confinement and sense of isolation distressing.<br>• Others are uneasy about the need to work in an environment that requires the use of such equipment. |
| 4. Respirator and Mask Dead Space | • It is very important that the individual not rebreathe exhaled air, and that the dead space in the mask be kept to <150 cc or that the mask be adequately ventilated to flush out the dead space. Otherwise there would be rebreathing of exhaled $CO_2$ and a deficiency in inspired $O_2$. |

EXHIBIT D-3 (2)

## GENERAL PROBLEMS ASSOCIATED WITH RESPIRATOR USE (Cont'd.)

| Problem Areas | Problems |
|---|---|
| 5. Design Problems Associated With the Eyepiece on Full-Face Masks | • They should not distort the vision.<br>• They do decrease the field of vision.<br>• If an individual wears glasses, the glasses can become fogged or the eyepiece itself may become fogged.<br>• The individual with bifocal vision may have difficulty in performing his task.<br>• It may be necessary to construct the eyepieces by means of special grinding with built-in lenses<br>• Anti-fogging compounds may have to be employed or a nose clip worn to prevent fogging of the eyepiece<br>• All of these can decrease efficiency and be uncomfortable and unpleasant for the individual. |
| 6. Speech Transmission | • Upon movement of the jaws, the mask may become distorted and leaks occur.<br>• It may be necessary to equip the masks with special diaphragms, microphones, amplifiers, and radios to provide ability for communication. |
| 7. People With Respiratory Diseases | • People who have bronchitis, emphysema or chronic asthma should not be employed in work using respirators.<br>• This limitation knocks out a large segment of the working population (approx. 32% of all males and females over the age of 35). |
| 8. Personnel Training in the Use of Respirators | • Personnel must be trained in respirator use, workings and care. |

## GENERAL PROBLEMS ASSOCIATED WITH RESPIRATOR USE (Cont'd.)

| Problem Areas | Problems |
|---|---|
| 9. Maintenance of Respirators | • Masks must be inspected monthly.<br>• They have to be cleaned and examined after each use. The washing should be done with soap and water or with detergent and allowed to be air or force dried.<br>• Occasionally it may be necessary to sterilize the mask, because it may become a source for bacterial contamination and disease transmission.<br>• Cleaning and repair stations have to be set up where masks or respirators are being used. |
| 10. Storage | • Storage is another factor that must be considered. Proper facilities must be provided to keep the respirators and their component parts in good condition. |

Source: Joseph F. Tomashefski, Head of Pulmonary Disease Department, The Cleveland Clinic, Statement presented to USDOL/OSHA Hearings on Vinyl Chloride; Occupational Exposure Hazard, June 25, 1974 and Snell assessment.

EXHIBIT D-4

USDOL/OSHA

SUMMARY OF THE STATEMENT OF
DR. MARCUS M. KEY AT OSHA HEARINGS - AIR
PURIFYING EQUIPMENT TO VINYL CHLORIDE MONOMER
BREAKTHROUGH TIMES

| Respiratory Device | Test Conditions | Breakthrough | Comments |
|---|---|---|---|
| Organic Vapor Cartridges | • VCM concentration: 50 ppm<br>• 50% R. H.<br>• Flow rate consistent with a moderately heavy work rate | • 10% breakthrough in 40 to 75 minutes<br>• Service life decreases as R. H. increases | • Because the odor threshold of VCM is considerably higher than the breakthrough concentration, it is the position of NIOSH that the only suitable respiratory protective devices for VCM are supplied respirators or positive mask self-contained breathing apparatuses. |
| Canister Gas M | • VCM concentration: 100 ppm<br>• 50% R. H.<br>• Flow rate consistent with a moderately heavy work rate | • 10% breakthrough in 200-350 minutes<br>• Service life decreases as R. H. increases | |
| Gas Mask Facepieces | • VCM concentration: 100 ppm<br>• 50% R. H.<br>• Flow rate consistent with a moderately heavy work rate | • 1% leakage | |

Source: Marcus M. Key, M.D., Director, NIOSH Center for Disease Control, Statement presented to USDOL/OSHA Hearings on Vinyl Chloride; Occupational Exposure Standard, June 25, 1974 and Snell assessment.

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EXHIBIT D-5 (1)

USDOL/OSHA

STATEMENT OF INDUSTRY REPRESENTATIVES ON HUMAN FACTORS RELATING TO PROTECTIVE CLOTHING AT THE OSHA HEARINGS

| Industry Representative | Clothing Type | Advantages | Disadvantages | Physiological Considerations | Human Factors | Comments |
|---|---|---|---|---|---|---|
| K. H. Oelhe[1] | Full impervious pressurized suit | Protective against vinyl chlorid[illegible] | Places worker in situation of unacceptable heat stress | A worker, while wearing such a suit in a test after 5 minutes sitting at 85° F ambient temperature, had a skin temperature of 100.9° F. After five additional minutes of slow walking the skin temperature was 101.8° F and the body temperature which had been 98.4° F at the beginning of the test, rose to 102.6° F. | Suit tends to be a safety hazard because of its bulkiness and limited visibility<br><br>Hearing is difficult<br><br>Communication with others is almost impossible | The use of this type suit should be limited to emergency situations |
| F.F. Hey[2] | Full body impervious air supplied suit | Prevents vinyl chloride gas from contacting body | Prevents body heat and moisture from passing to the atmosphere<br><br>Garment would guarantee long-term exposure to VCM if, by chance, some of the gas entered the garment | The heat and discomfort produced will produce fatigue reducing employee alertness<br><br>Perspiration generated by the suits will cause severe discomfort | Reduction of employee efficiency due to cumulative effects of fatigue, unsure footing<br><br>Reactor cleaners, required by their job to be sure footed, will be greatly impaired by bulk of suit<br><br>Employee efficiency will drop as much as 75% when such suits are worn | Premium wages will be required to induce employees to wear suits<br><br>Recognizing the fact that the suits represent a safety hazard, the Secretary of Labor did not require their use in the carcinogen standards<br><br>Because reactor cleaners are identified as a group of maximum risk they should be supplied with "protective" rather than impervious clothing and gloves in order to protect them from skin contact |
| | Impervious gloves | Prevents vinyl chloride from contacting hands | Gloves will diminish employee's dexterity | | Operators will find it difficult to operate controls and keep records, and maintenance men, particularly instrument and electrical repairmen, will not be able to perform their jobs safely and properly | |

EXHIBIT D-5 (2)

| Industry Representative | Clothing Type | Advantages | Disadvantages | Physiological Considerations | Human Factors | Comments |
|---|---|---|---|---|---|---|
| H.H. Fawcett(3) | Air supplied suit | Designed for exactly the kind of situation as reactor cleaning | | | People could work for long periods of time wearing air supplied suits if the air were directed throughout the suit.<br><br>Equipment can be used if people are educated to use it and know the advantages and necessity for using it | People don't want this type of equipment because it is trouble and costs money |

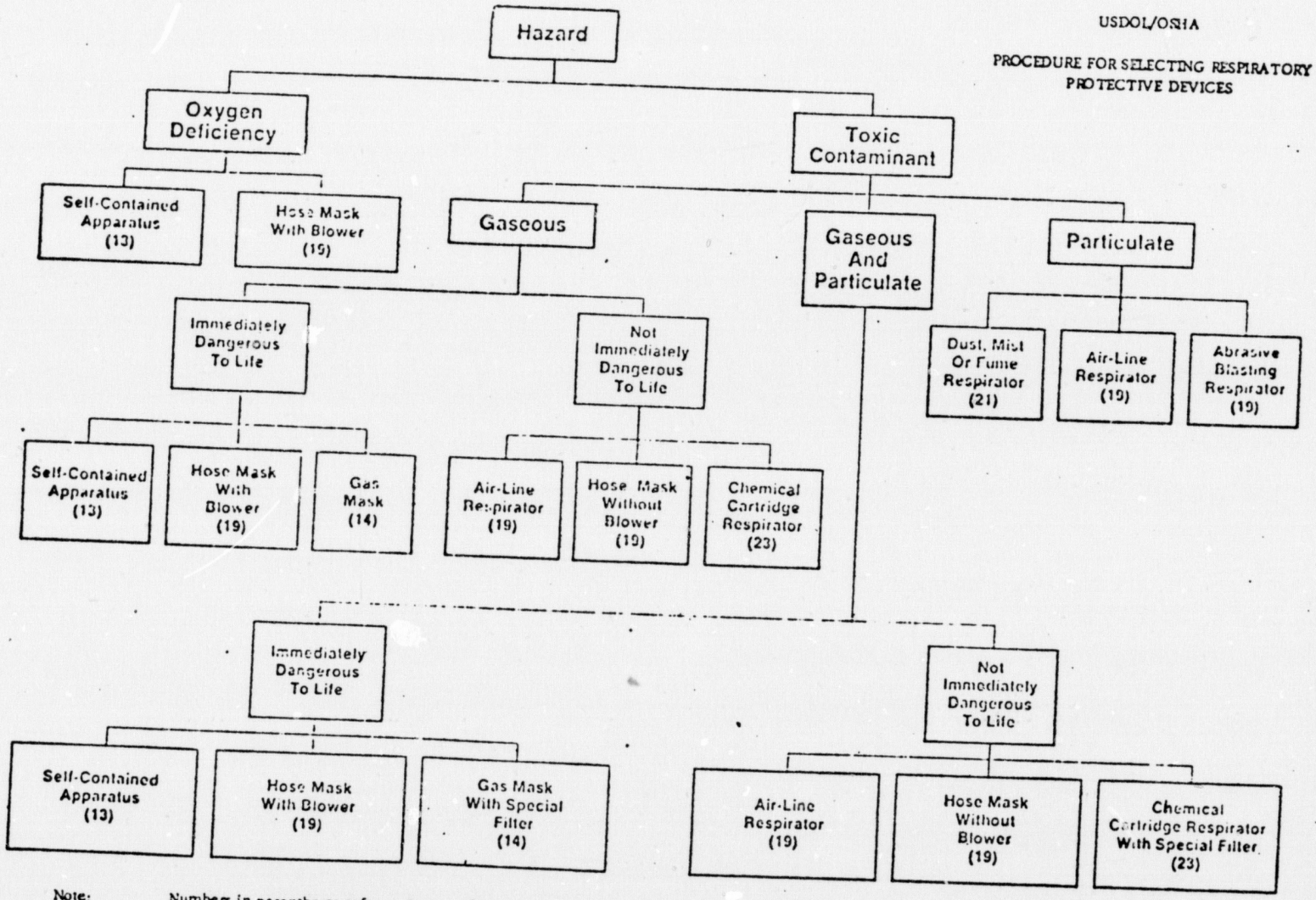
Sources: (1) Written submission by K. H. Oelfke, Production Manager at the Texas Division of Dow, Chemical U.S.A. presented at the USDOL/OSHA Hearing on the proposed permanent standard for occupational exposure to vinyl chloride, June 28, 1974
(2) Statement of F.F. Hoy, plant manager, Firestone Plastics Company, Berryville, Maryland presented at USDOL/OSHA Hearing on the proposed permanent standard for occupational exposure to vinyl chloride, July 1st, 1974
(3) Statement of H.H. Fawcett, Chairman of the Committee on Chemical Safety of the American Chemical Society at the USDOL/OSHA Hearings on the proposed permanent standard for occupational exposure to vinyl chloride, July 9, 1974.
(4) Shell assessment.

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EXHIBIT D-6

USDOL/OSHA

PROCEDURE FOR SELECTING RESPIRATORY PROTECTIVE DEVICES




Note: Numbers in parentheses refer to Bureau of Mines Schedules and Revisions thereof.

Source: After Bureau of Mines information circular 7792

EXHIBIT D-7 (1)

USDOL/OSHA

COMPARISON OF RESPIRATORY PROTECTION DEVICES

| Respiratory Device | Application | Method of Operation | Limitations | Useful Life | BuMines Approval | Comments |
|---|---|---|---|---|---|---|
| 1. Air Purifying Devices | Air Purifying Devices remove contaminants from the atmosphere. | Various chemicals remove specific gases and vapors and mechanical filters remove particulate matter. | Can be used only in atmospheres containing sufficient oxygen to sustain life (at least 16% by volume at sea level) and within specified concentration limitations of the specific device.<br><br>Mechanical filter respirators do not provide against gases, vapors or oxygen deficiency. | The useful life of an air purifying device is dependent upon the concentration of the contaminants, the breathing volume of the wearer, and the capacity of the air purifying medium. | | |
| (1) Mechanical Filter Respirators | Mechanical Filter Respirators provide respiratory protection against particulate matter such as non-volatile dusts, mists, or metal fumes. Selection of the appropriate respirator is based on the type, toxicity, and particle size of the particulate matter. | They consist essentially of a soft resilient facepiece of either half-mask or full-face design, to which is directly attached one of several types of mechanical filters made up of some fibrous material which removes the harmful particles by physical trapping as air is inhaled through the material. Gaseous matter such as air itself will pass through the filter, but solid or liquid particles are trapped in much the same manner as rocks and pebbles are separated from sand in a screening process. The filter must be highly efficient however to stop the small harmful particles. | | | Schedule 21 | Other than the difference between a half-mask facepiece and a full facepiece, which is used when the particulate exposure is harmful or irritating to the eyes as well as the respiratory tract, the filter is the most essential distinction among classes of respirators. The most desirable compromise must be worked out for each class with respect to breathing area (size), resistance to breathing, efficiency in filtering particulates of specific size ranges and time required to clog the filter. |
| (2) Chemical Cartridge Respirators | Chemical Cartridge Respirators afford protection against light concentrations (.05% to .1% by volume, depending upon the contaminant) of certain acid gases, alkaline gases, organic vapors, and mercury vapor by utilizing various chemical filters to purify the inhaled air. | They differ from mechanical filter respirators only in that they use small cartridges containing chemicals to remove harmful gases and vapors. | Chemical Cartridge Respirators are non-emergency respiratory protective devices and should never be used in immediately dangerous atmospheres, except for escape purposes.<br><br>However, to clarify this general statement, it will be well to list four other major negative rules which apply to Chemical Cartridge Respirators:<br><br>• Do not use Chemical Cartridge Respirators for protection against gaseous material which is extremely toxic in very small concentrations (carcinogens such as VCM).<br><br>• Chemical Cartridge Respirators should not be used for exposures to harmful gaseous matter which cannot clearly be detected by odor (such as VCM in concentrations < 250 ppm). | | Schedule 23 | Mouthpiece type chemical cartridge respirators offer protection against intermittent exposure to light concentrations of gases and vapors or may be used for self-rescue in times of catastrophe. The mouthpiece design promotes compactness--such a respirator can be conveniently carried by the workman during all working hours or stored conveniently near the work location for immediate availability.<br><br>Combination mechanical filter-chemical filter respirators utilize dust, mist, or fume filters with a chemical cartridge for dual or multiple exposure. Respirators with independently replaceable mechanical filters are preferred for this type because the dust filter normally plugs before the chemical cartridge is exhausted. One combination mechanical-chemical filter respirator employs a back mounted filter element and is especially well suited for spray painting and welding operations, where the air contaminant is concentrated in front of the worker. |

| Respiratory Device | Application | Method of Operation | Limitations | Useful Life | BuMines Approval | Comments |
|---|---|---|---|---|---|---|
| | | | . Chemical Cartridge Respirators should not be used against any gaseous material in concentrations which are highly irritating to the eyes.<br><br>. Obviously, Chemical Cartridge Respirators cannot be used for protection against gaseous material which is not effectively stopped by chemical fills utilized, regardless of concentration. | | | |
| (3) Gas Masks | Gas masks have been used effectively for many years for respiratory protection against certain gases, vapors and particulate matter which otherwise might be harmful to life or health. They provide simplicity of operation, compactness, ease of maintenance and economy. | Use large canisters mounted on wearers torso, same principle of operation as in the cartridge systems. Some canisters located on chin. Canisters differ from cartridges in that they are much larger than the latter. | Because gas masks are air purifying devices, designed solely to remove specific contaminants from the air, it is essential that their use be restricted to atmospheres which contain sufficient oxygen to support life (at least 16% by volume at sea level) and which contain generally no more than 2% concentrations of toxic gases and vapors by volume. | The service life of an air purifying canister type gas mask depends on the following factors:<br><br>. The design, including the quality and amount of chemical fill; packing uniformity and density.<br><br>. Variable exposure conditions, including concentration of contaminants in the air, breathing rate of the wearer, temperature and humidity. Generally, higher concentrations, breathing rates and humidity conditions adversely affect service life. Since the exposure conditions are subject to wide variation, it is most difficult to estimate the service life of a gas mask canister. However, for guidance purposes, actual man tests performed under Bureau of Mines Schedule 14F stipulate the following minimum service requirements at an average breathing rate of 25 liters per minute in concentrations of 2% for most gases and vapors of 2% ammonia:<br><br>- Industrial Size<br>..Canisters — 30 minutes<br><br>- Type N. Canister<br>..Acid Gases — 15 minutes<br>..Organic Vapors — 25 minutes<br>..Ammonia — 15 minutes<br>..Carbon Monoxide — 30 minutes<br><br>Super Size Canisters, because of their greater volume of chemical fill, will last approximately twice as long as the equivalent Industrial Size Canister. Chin Style Canisters, because of their small size, should be used in concentrations not in excess of 0.5%. | Schedule 14 | Canister Replacement<br><br>It is generally recommended that gas mask canisters used for emergency purposes should be replaced after each use. Specific indications for canister replacement and/or return to fresh air are:<br><br>. If canisters with window indicators show the specified color changes.<br><br>. If any leakage is detected by smell, taste, eyes, nose or throat irritation.<br><br>. If high breathing resistance develops.<br><br>. If the canister shelf life is exceeded.<br><br>Warning Signs<br><br>Specific warning signs which require immediate return to fresh air are:<br><br>. Uncomfortable heat in the inhaled air. (A properly operating canister will become warm on exposure to certain gases or vapors, but a canister which becomes extremely hot indicates that concentrations above the canister limit have been encountered.)<br><br>. If nausea, dizziness or signs of distress develop. |

| Respiratory Device | Application | Method of Operation | Limitations | Useful Life | BuMines Approval | Comments |
|---|---|---|---|---|---|---|
| B. Supplied Air Devices | Provide air from outside source for long periods of time. | Deliver breathing air through a supply hose connected to the wearers facepiece. | Shall be used only in atmospheres not immediately harmful to life. Air source must be located in clean air and monitored frequently. | As long as air is supplied and wearer is comfortable. | Schedule 19 | |
| (1) Air Line Respirators | | The air-line respirator is connected to a suitable compressed air source by a hose of small inner diameter and air is delivered to the user continuously or intermittently in sufficient volume to meet the wearer's breathing requirements. | Air-Line Respirators shall be used only in atmospheres not immediately harmful to life or from which the wearer can escape without the use of the respirator. This limitation is necessary because the air-line respirator is entirely dependent upon an air supply which is not carried by the wearer of the respirator. If the air supply fails, the wearer is without respiratory protection and might not escape from the immediately hazardous atmosphere. Another limitation of air-line respirators is that the air supply hose limits the wearer to a fixed distance from the air supply source.<br><br>The Bureau of Mines approves air-line respirators under Schedule 19 which has the following significant requirements. The maximum hose length for which approval is granted is 250 feet, and the maximum permissible inlet pressure is 125 psig. Approval is sought for specific hose lengths and inlet pressures, with the longest hose lengths for which approval is sought assembled to the respirator, and the lowest inlet pressure introduced to the air supply hose, constant flow units must deliver at least four cubic feet per minute (CFM) measured at the facepiece. The exhalation resistance at 85 liters per minute shall not exceed one (1) inch of water-column height.<br><br>When helmets or hoods are used, the same requirements must be met except that the flow rate must be at least six (6) cubic feet per minute. For both types of assemblies with the highest inlet pressure and shortest hose length, the maximum flow shall not exceed fifteen (15) cubic feet per minute. | | | Accessory equipment such as pressure regulators, pressure relief valves and air filters may be necessary to ensure that the air is at the proper pressure and quality for breathing.<br><br>Air-line respirators are furnished in many types, but there are three basic classes. There are constant flow, demand flow and pressure demand flow, with the respirators equipped with half masks or full facepieces. If eye protection is required, a full facepiece must be used.<br><br>The air supply is the responsibility of the user, and the air-line respirator is approved for use only when it supplies respirable air at the correct pressure and flow. The compressed air shall meet the most recent requirements of Compressed Gas Association Specification G-7.1 for Type 1, Class D gaseous air. This currently requires that the carbon monoxide level not exceed 20 parts per million (ppm), the carbon dioxide content not exceed 1000 ppm, and condensed hydrocarbons not exceed 5 milligrams per cubic meter.<br><br>With internally lubricated piston-type compressors, overheating may produce carbon monoxide, so routine testing for carbon monoxide or the installation of a constant monitoring analyzer is desirable.<br><br>Some air compressors are manufactured specifically to provide respirable air. They use compression seal liquids such as water or diaphragms for delivering the air. |
| • Constant flow types | Constant flow units are normally used where there is an ample air supply such as provided by an air compressor.<br><br>Constant-Flow Air-Line Respirators with facepieces alone are used where respiratory protection only is needed. A hood can be added to the facepiece for protection against sand or dust blast and frequently a helmet is used for this application with a hood or cape fitted to it. Such units are used also for lead grinding. | | | | | |

| Respiratory Device | Application | Method of Operation | Limitations | Useful Life | Bulletins Approval | Comments |
|---|---|---|---|---|---|---|
| • Demand types | Demand type are generally used where only compressed air cylinders are available. | Demand type air-line respirators with half masks or full facepieces deliver air flow only during inhalation with exhalation to the atmosphere. | A suitable pressure regulator is required to ensure that the air is at the proper pressure for breathing. The same requirements for approval apply to the demand type as to the constant flow units, except the minimum flow at a maximum resistance of two (2) inches of water-column height measured at the facepiece shall be at least four (4) cubic feet a minute and not more than fifteen (15) cubic feet a minute with all hose lengths within the inlet pressure range for which approval is sought. The exhalation resistance at 85 litres per minute shall not exceed one (1) inch of water. | | | |
| • Pressure demand types | For those conditions where the possible inward leakage caused by the negative pressure during inhalation always present in demand systems is unacceptable and there can't be the relatively high air consumption of the constant flow units. | It peovides a positive pressure during both inhalation and exhalation. | It must meet the same requirements for demand systems except that the static pressure in the facepiece shall not exceed 1.5 inches of water, the exhalation resistance at 85 liters/minute shall exceed the static pressure in the facepiece by more than 2.0 inches of water and that there be at least 4 CFM air flow during inhalation before a negative pressure is developed in the facepiece. | | | |
| (2) Hose Masks | | | | | | |
| • With blowers | Hose masks with blowers may be approved by Bureau for respiratory protection in any atmosphere regardless of the degree of contamination or oxygen deficiency, providing clean, breathable air can be reached within the distance of the permissible hose length. | Blower forces air into mask. | Hose masks with blowers can be used with up to 300 ft. of hose. The blower should always be used with this type of equipment. Only hand driven blowers are currently approved.<br><br>The air hose must have a large inside diameter, approximately one inch, so, in case of blower failure, the wearer can breathe through the hose while escaping from the contaminated area; and it must be highly resistant to petroleum vapors as well as be able to withstand crushing weight. That accounts for the heavy wire reinforced construction of hose-mask hoses. | | | The entire hose mask assembly, including facepieces, harness, air hose, and blower, is usually packaged in a portable trunk. The blower operator serves also as a standby or guard, ready to aid the workman in case of mishap. |
| • Without blowers | Hose masks without blowers are used when uncontaminated air can be reached within a distance of 75 feet. | Wearer forces air into mask through his own breathing. | Can only be used up to a distance of 75 feet. Those units, however, carry only limited approval and cannot be used in atmospheres immediately harmful to life. Bureau of Mines Approval. | | | |

EXHIBIT D-7 (5)

| Respiratory Device | Application | Method of Operation | Limitations | Useful Life | BuMines Approval | Comments |
|---|---|---|---|---|---|---|
| 3. Self-Contained Breathing Apparatus | Self-contained breathing apparatus provide complete respiratory protection in toxic gases and where there is oxygen deficiency. The wearer is independent of the surrounding atmosphere because he is breathing with a system admitting no outside air. The oxygen or air supply of the apparatus itself takes care of respiratory require ments. | Self-contained breathing apparatus are divided into three basic types--oxygen cylinder rebreathing, demand, and self-generating. | Major problem or limitation is bulkiness of apparatus. | Dependent on size of air cylinders and, in the case of the rebreathing types, on the $CO_2$ removal container. | Schedule 13 | |
| a) Oxygen Cylinder Rebreathing and Self-Generating Types | | The oxygen cylinder rebreathing type in use today is the "lung-governed" type which automatically compensates for the varying breathing demand of the user. It consists of a relatively small cylinder of compressed oxygen, reducing and regulating valves, a breathing bag, facepiece or mouthpiece plus nose clip, and a chemical container to remove carbon dioxide from the exhaled breath.<br><br>The self-generating type uses the principle of rebreathing; but it has no mechanical operating components. Both types function in the same manner and will be discussed together.<br><br>The high-pressure oxygen from the cylinder is reduced in pressure to a breathing level by means of a reducing and regulating valve. In some units there is a constant flow plus a lung-controlled valve which adds any required additional flow. Other apparatus have only an admission valve which delivers the oxygen from the breathing bag to the wearer's face.<br><br>Exhaled breath passes down another tube into the container holding the carbon dioxide removing chemical and then through a cooler. Finally, the purified exhalation flows into the breathing bag where it mixes with the incoming oxygen from the cylinder.<br><br>The rebreathing principle permits the most efficient utilization of the oxygen supply. The exhaled breath contains both oxygen and carbon dioxide as the human body extracts only a small part of the oxygen inhaled. | The oxygen cylinder must be refilled and the carbon dioxide-removing chemical replaced after each use. As is true of all respiratory protective equipment, training in proper use and maintenance is essential for the most efficient operation.<br><br>The one hour service life for the self-generating type apparatus is based on test procedures of Bureau of Mines Approval Schedule 13 and in use a lesser or longer protection period may result based on the user and his level of exertion. | The types of cylinder rebreathing units now manufactured are approved by the Bureau of Mines for two, three or four hour duration.<br><br>The self-generating type apparatus is approved by the Bumines for one hour. | | The self-generating breathing apparatus differs from conventional cylinder rebreathing apparatus in that it utilizes a chemical canister which evolves oxygen and removes the exhaled carbon dioxide in accordance with breathing requirements. It eliminates high pressure cylinders, regulating valves, and other mechanical components.<br><br>The canister, which contains potassium superoxide, evolves oxygen when contacted by the moisture and carbon dioxide in the exhaled breath, and retains the carbon dioxide and moisture. Retaining moisture is important as it aids in preventing lens fogging.<br><br>In use, the self-generating unit operates as other rebreathing apparatus except that the wearer, using the canister, makes his own oxygen instead of drawing from a compressed gas cylinder. The outstanding features of this type are its simplicity of construction and use, and lesser need for maintenance when compared with high pressure apparatus.<br><br>There are several methods for refilling or recharging high pressure air or oxygen cylinders. Compressors are sometimes used, but the simplest and most convenient method is to cascade from large supply to small apparatus cylinders. |

| Respiratory Device | Application | Method of Operation | Limitations | Useful Life | Bu.Mines Approval | Comments |
|---|---|---|---|---|---|---|
| | | As the user exhales into the container, the carbon dioxide is removed by the chemical and the oxygen which is left is reused. That method of operation applies to all oxygen cylinder rebreathing type apparatus as well as to the self-generating type. | | | | |
| (2) Demand Type | Demand-type apparatus are available in different models for specific applications.<br><br>Of particular application to some industries is a short duration unit known as an "escape mask." It is normally worn by a worker at times when he is in an area where a potentially toxic atmosphere, above the capacity of a gas mask exists. Areas to which high pressure gases are piped fall into this category. Another type of short duration unit is put on at the time escape is necessary.<br><br>A work mask type of apparatus is used for planned maintenance work. The apparatus is actually a two-fold unit.<br><br>• A self-contained apparatus with which the wearer can move freely about by using a small cylinder to enter or leave the toxic atmosphere--either routinely or in the failure of the main breathing supply.<br><br>• There is a provision for connecting a hose to the demand regulator so that the wearer can breathe during the work period from a large cylinder which has a pressure reducing valve attached to provide low pressure for the connecting hose. Manifold assemblies can be provided to permit more than one worker to work from a common breathing source. It is imperative that the small emergency cylinder be used with this type of apparatus; otherwise, a failure of the supply from the large cylinder would expose the wearer to the toxic atmosphere. | All consist of a high pressure cylinder, a demand regulator connected either directly or by high-pressure tube to the cylinder, a facepiece and tube assembly with an exhalation valve or valves, and a method of mounting the complete apparatus on the body. In use, the wearer turns on the cylinder valve after putting on the facepiece, inhales at breathing pressure through the demand regulator to the facepiece and then exhales through a valve in the facepiece to the surrounding atmosphere. | All demand apparatus are relatively inefficient when compared with the rebreathing type, because the exhaled oxygen is released to the atmosphere instead of being re-used.<br><br>Work mask types are limited by the connecting hose which limits the free movement of the wearer to the length of the hose. It is not an emergency type unit as, for use, it requires setting up some auxiliary equipment.<br><br>The duration of the demand type apparatus depends on such factors as:<br><br>• The degree of physical activity of the user;<br><br>• The degree to which the user's breathing is increased by excitement, fear or other emotional factor;<br><br>• The degree of training or experience which the user has had with this or similar equipment; whether or not the cylinder is fully charged at the start of the work period;<br><br>• The possible presence in the compressed air of carbon dioxide concentrations greater than the .04% normally found in atmospheric air;<br><br>• The atmospheric pressure<br><br>• The condition of the apparatus<br><br>Under the current Schedule 13E, all demand type apparatus must satisfy tests conducted at -25°F. Although low temperature components such as nose-cups to reduce fogging may be added if needed. | Typical demand type apparatus such as the MSA "Air Cub" are certified by Bumines for 15 minutes. Others such as the MSA "Air Mask" are certified for 30 minutes under schedule 13 for entry into and escape from irrespirable atmospheres. These service life ratings are based on tests by the Bureau of Mines on men performing moderate to heavy work in each of the different types of work tests or breathing machine tests at a rate of 40 liters per minute. The user should not expect to obtain the exact rated service life on each use. The work being performed may be more or less strenuous. | | The term, demand regulator, means that the air flow is on inhalation demand, automatically regulating itself to the desired level to compensate for variations in breathing needs.<br><br>Demand apparatus depend upon watching a pressure gauge to learn when the breathing supply has dropped to a point where the user must return to fresh air. A self-actuating warning device is required for bureau of Mines Approval. The warning device can be either audible or use increased breathing resistence to alert the wearer to return to fresh air. |

Source: Basic Elements of Respiratory Protection, Mine Safety Appliances and Shell Telephone Survey of Respiratory Equipment Industry.

EXHIBIT D-8(1)

USDOL/OSHA

COSTS AND AVAILABILITY OF TYPICAL RESPIRATORY DEVICES

| Respiratory Device/Manufacturer | Components: Catalog Number | Components: Description | Lot Size | Cost Per Unit (1974 Dollars) | Availability (Weeks To Receive After Order) |
|---|---|---|---|---|---|
| 1. Air Purifying Devices | | | | | |
| (1) Mechanical filter respirators | | | | | |
| • Bausch and Lomb (B&L) | R 10 | Provides protection against dusts (single cartridge). | Up to 50 units | $ 7.35 | Stock item |
| | R 20 | Same as above but with dual cartridge. | | 8.90 | Stock item |
| | 5-15-10 | Replacement filters. | Pack of 50 | 0.26 | Stock item |
| • Mine safety apparatus (MSA) | 96000 | Dustfoe 77 provides protection from dusts and mists having a TLV of not less than 2.4 million particles/cu. ft. | 24-71 | 7.25 | Stock item |
| | 96106 | Filters | Pack of 50 | 0.13 | Stock item |
| | 79983 | Dustfoe provides protection against finely divided aerosols up to 0.3 microns diameter (99.98% effective). | 72-143 | 8.55 | Stock item |
| | 79984 | Type "H" cartridge. | 144 and up | 2.55 | Stock item |
| • Scott | 8201-R | Duo-seal dual cartridge high efficiency dust filter (0.3 micron particles). | 50-99 | 9.00 | Stock item |
| | 8004-R | Replacement cartridge. | | | |
| | 8101-R | Same as above respirator but single cartridge. | 50-99 | 8.99 | Stock item |
| | 502-R | Replacement cartridge. | 50-99 | 2.80 | Stock item |
| • Welsh | 7680 | Protex dual cartridge respirator for dusts with TLV more toxic than 0.1 mg/m$^3$ full face mask. | 1 | 45.75 | |
| | 7600-8 | Replacement cartridge. | 4 | 1.34 | |
| | 7406 | Protex single cartridge half face mask. | 72-143 | 5.50 | |
| | 7500-6B | Static wool filter replacement. | 72-143 packages of 100 ea. | 0.13 | |
| (2) Chemical cartridge respirators | R 21 | Provides protection against low concentrations of organic vapors. | 50-99 | 10.70 | |
| • B&L | 5-15-21 | Organic vapor catridge replacement for R 21. | 50-99 boxes of 6 | 1.51 | Stock item |
| • MSA | 85556 | MSA chemical cartridge respirator for protection against organic vapors (0.1%). | 72-143 | 9.70 | Stock item |
| | 44135 | Replacement cartridge for 85556. | 100-149 | 1.45 | Stock item |
| | 76853 | MSA same as 85556 but with single cartridge for organic vapor. | 72-143 | 9.30 | Stock item |
| | 76883 | Replacement cartridge for 76853. | 100-149 | 2.65 | Stock item |

EXHIBIT D-8 (2)

| Respiratory Device/Manufacturer | Components: Catalog Number | Components: Description | Lot Size | Cost Per Unit (1974 Dollars) | Availability (Weeks To Receive After Order) |
|---|---|---|---|---|---|
| . Scott | 8201-OV | Duo-seal respirator for organic vapors. Dual cartridge | 50-99 | $ 9.00 | Stock item |
| | 82004-OV | Replacement cartridge for 8201-OV | 100-499 pr. | 2.50 | Stock item |
| | 8101-OV | Same as 8201-OV but with single cartridge | 100-499 | 8.30 | Stock item |
| | 502-OV | Replacement cartridge for 8101-OV | 100-499 | 2.30 | Stock item |
| . Welsh | 7601 | Full-face respirator for organic vapors. Dual cartridge | 1 | 45.95 | |
| | 7500-1 | Replacement cartridge for 7601 | 72-143 packs with 6 pieces/pack | 1.28 | |
| (3) Gas masks | | | | | |
| . MSA | 457081 | MSA industrial size for up to 2% by volume organic vapors and toxic dusts with full face mask and body mounted canister | 6-11 | 78.05 | Stock item |
| | 77705 | Replacement canister for 457081 | 12-71 | 7.45 | Stock item |
| | 457112 | MSA chin type mask for up to 0.5% by volume organic vapors | 6-11 | 53.90 | Stock item |
| | 88339 | Replacement canister for 457112 | 100 and up | 5.85 | Stock item |
| . Scott | 679-1 | Chest style gas mask for up to 2% by volume organic vapor protection with full facepiece | 18 and up | 75.43 | 3 weeks |
| | 184-OV | Replacement canister for 679-1 (1000cc) | 12-71 | 6.50 | Stock items |
| | 661-1 | Chin style gas mask for organic vapor protection (full face) | 18 and up | 42.16 | Stock item |
| | 282-OV-L | 600cc replacement canister for 656-1 | 50-99 | 5.10 | Stock item |
| 2. Supplied Air Devices | | | | | |
| (1) Air line respirators | | | | | |
| . Constant flow | | | | | |
| - MSA | 457162 | Ultra-Vue facepiece and low pressure control valve (10-15 psig with 50 foot hose) | 1 | 82.30 | Stock item |
| | 457161 | Same as 457162 box with hyper-flo control valve (40-100 psig with up to 250 feet of air-hose) | 1 | 82.30 | Stock item |
| - Scott | 4622-10 | Zephyrair-complete full vision mask with belt mounted filter body and manual control valve. Adjust air pressures as follows with 3/8" ID hose<br>Hose Length: 15' to 50' — Pressure at Hose Inlet: 8 to 17 psi<br>Hose Length: 50' to 250' — Pressure at Hose Inlet: 17 to 30 psi | 18 and up | 60.94 | 2 weeks |

EXHIBIT D-8 (3)

| Respiratory Device/Manufacturer | Components: Catalog Number | Components: Description | Lot Size | Cost Per Unit (1974 Dollars) | Availability (Weeks To Receive After Order) |
|---|---|---|---|---|---|
| • Demand types | 7600A | Low pressure (10-25 psi) full facepiece. | 1 | $ 57.85 | |
| - MSA | 457157 | Mask-mounted demand air-line respirator w/ultra-vue facepiece 30-125 psi/15-250 ft. hose lengths. | 1 | 95.90 | Stock item |
| | 457165 | Belt mounted demand flow air-line respirator w/ultra-vue facepiece 30-125 psi/15-250 ft. hose lengths. | 1 | 95.90 | Stock item |
| - Scott | 4637-1 | Demand type respirator w/full vision mask 50-125 psi/ 15-250 ft. of hose length. | 18 and up | 75.43 | 3 weeks |
| • Hose masks/MSA | 457140 | One man combination hose mask, with hand operated blower (centrifugal) and 50 ft. of hose. | 1 | 668.00 | 60-90 days |
| | 457142 | Same as 457140 but is a two man unit. | 1 | 972.00 | 60-90 days |
| • Accessories for air-line systems | | | | | |
| - Compression systems/MSA | 32057 | "Clear air" blower that washes, cools, and humidifies air for 12 masks (Nash Co. compressor) | 1 | 2,586.00 | 16-18 weeks |
| | 81857 | Air-line filter for removal of dusts, mists, fumes as a final. | 1 | 44.55 | Stock item |
| | 46727 | Replacement chemical cartridge for 81857 filter (2 required). | 1-71 | 2.40 | Stock item |
| | 79030 | Particulate element replacement for 81857 filter. | 1 | 4.80 | Stock item |
| | 66716 | MSA pressure regulator reduces plant-compressor air pressure to the rated valve for the equipment. | 1 | 34.90 | Stock item |
| | 66709 | Pressure relief valve-16 psig. | 1 | 9.80 | Stock item |
| | 68265 | Pressure relief valve-25 psig. | 1 | 14.65 | Stock item |
| - Pressure regulators/MSA | 68858 | Required accessory when air-line respirators are operating from a high pressure cylinder<br>0-4000 psi hi-pressure gauge<br>0-200 psi low-pressure gauge. | 1 | 94.35 | Stock item |
| - Air-lines and manifolds/MSA | 455020 | Air hose - 15 ft. long | 1 | 16.65 | Stock item |
| | 455021 | Air hose - 25 ft. long | 1 | 23.95 | Stock item |
| | 455022 | Air hose - 50 ft. long | 1 | 43.20 | Stock item |
| | 93031 | Manifold-4 man (snap-tite) | 1 | 59.20 | 30 days |

EXHIBIT D-8 (4)

| Respiratory Device/Manufacturer | Components: Catalog Number | Components: Description | Lot Size | Cost Per Unit (1974 Dollars) | Availability (Weeks To Receive After Order) |
|---|---|---|---|---|---|
| 3. Self Contained Respirators | | | | | |
| (1) Pressure demand-full-facepiece self-contained breathing apparatus 1, 2 MSA | 95069 | With single lens clear-vue facepiece and audible alarm | 1 | $515.00 | Two weeks |
| (2) Combination pressure demand full facepiece respirator and pressure-demand self-contained breathing apparatus 1, 2 MSA | 96395 | Complete in carrying case | 1 | 699.00 | Two weeks |
| (3) Positive pressure full facepiece self-contained breathing apparatus 1, 2 | Would be very wasteful of compressed air | | | | Not available |
| (4) Combination continuous flow respirator and a pressure demand self-contained breathing apparatus 1, 2 | Would be very wasteful of compressed air | | | | Not available |
| (5) Demand work mask w/quick-connect/disconnect assembly which can be attached to primary air supply MSA | 457159 | MSA unit complete with ultra-vue facepiece assembly, speaking diaphragm, demand regulator, harness, and 12 cu. ft. capacity air cylinder in carrying case | 1 | 496.00 | 2 weeks |
| 4. Cylinder Recharger Systems MSA | | | | | |
| | | Cascading System for Cylinder Recharging | | | |
| | 68850 | Air coupler tee | 1 | 17.50 | Stock item |
| | 69851 | Air pigtail | 1 | 22.95 | Stock item |
| | 68846 | Air outlet connection, complete with gauge | 1 | 34.90 | Stock item |
| | 77263 | High pressure airfilling hose, 5 ft. long. | 1 | 24.30 | Stock item |

Notes: (1) Permitted types under the temporary 50 ppm standard.
(2) Permitted types under the proposed permanent no detectable standard.
(3) Stock items are delivered in not more than one week.

Sources: Bausch & Lomb Safety Products Division Catalog, 1974.
Mine Safety Appliances Respiratory Protection Catalog, 1974.
Scott/Acme Products Respiratory Protection Equipment and Accessories Catalog, 1974.
Welsh Catalog 72R, 1974.
Results of Snell survey of the respiratory equipment manufacturers.

# VI. CONCLUSIONS AND RECOMMENDATIONS

This chapter addresses the conclusions and recommendations of the report based on the findings and economic analysis of the previous section.

## 1. ACHIEVING "NO DETECTABLE" LEVELS OF VCM PRINCIPALLY THROUGH ENGINEERING MEANS IS JUDGED NOT FEASIBLE WITH PRESENT TECHNOLOGY BOTH IN THE VCM AND PVC SECTORS

- Based on the industry surveys and Snell's independent assessments of the state-of-the-art of the technology, it is concluded that achieving "no detectable" (0 - 1 ppm) VCM levels in the VCM industry is not feasible principally through engineering means. Reasons include the following:

  - technology, including state-of-the-art developments, is not available to eliminate VCM leaks and fugitive losses
  - existing plants have not been designed for total VCM containment
  - there is no design or operating experience in the industry aimed at maintaining very low VCM levels
  - no direct technology transfer opportunities are known to enable development of designs for "no detectable" levels in new plants.

- Based on the industry surveys and Snell's independent assessments of the state-of-the-art of the technology, it is concluded that achieving "no detectable" (0 - 1 ppm) VCM levels in the PVC industry is not feasible principally through engineering means. Reasons include the following:

  - PVC manufacture is a batch operation
  - Technology, including state-of-the-art developments is not available to eliminate VCM leaks and fugitive losses

- existing plants have not been designed for total VCM containment

- there is no design or operating experience in the industry aimed at maintaining very low VCM levels

- no direct technology transfer opportunities are known to enable development of designs for "no detectable" levels in new plants.

- Up to four years of development is estimated to reduce residual VCM levels below 100 ppm in PVC products on the basis of output volume.

- The technology including state-of-the-art developments is not available to reach very low or "no detectable" residual VCM levels on the basis of output volume.

2. THE COSTS OF COMPLIANCE INCREASE RAPIDLY WITH DECREASING VCM TARGET LEVELS AND REPRESENT SIGNIFICANT ENGINEERING UNCERTAINTY OR INFEASABILITY BEYOND 10 PPM CEILING AND 2 - 5 PPM TWA FOR THE VCM INDUSTRY AND 15 - 25 PPM CEILING AND 10 - 15 TWA FOR THE PVC INDUSTRY

- The analysis which follows indicates the cost sensitivity of attempting to reach very low VCM levels in the VCM industry.

| VCM Target Level (ppm) | Standard Price (¢/lb.) | Price Index | Percent of VCM Industry Capacity Endangered | Time To Reach Level Via Engineering Controls (years) |
|---|---|---|---|---|
| Historical Practice | 7.41 | 1.00 | Not Applicable | Not Applicable |
| 50 ceiling | 7.47 | 1.01 | 0% | 0.5 |
| 25 ceiling | 7.59 | 1.02 | 0% | 2.5 |
| 10 ceiling and 2-5 TWA | 7.69 | 1.04 | 0% | 3.0 |
| Extrapolated Attempt to Reach "No Detectable" Levels | 12.71 | 1.72 | 100% @ "No Detectable" Levels | Not Estimated |

Source: Exhibits V-15 and V-13

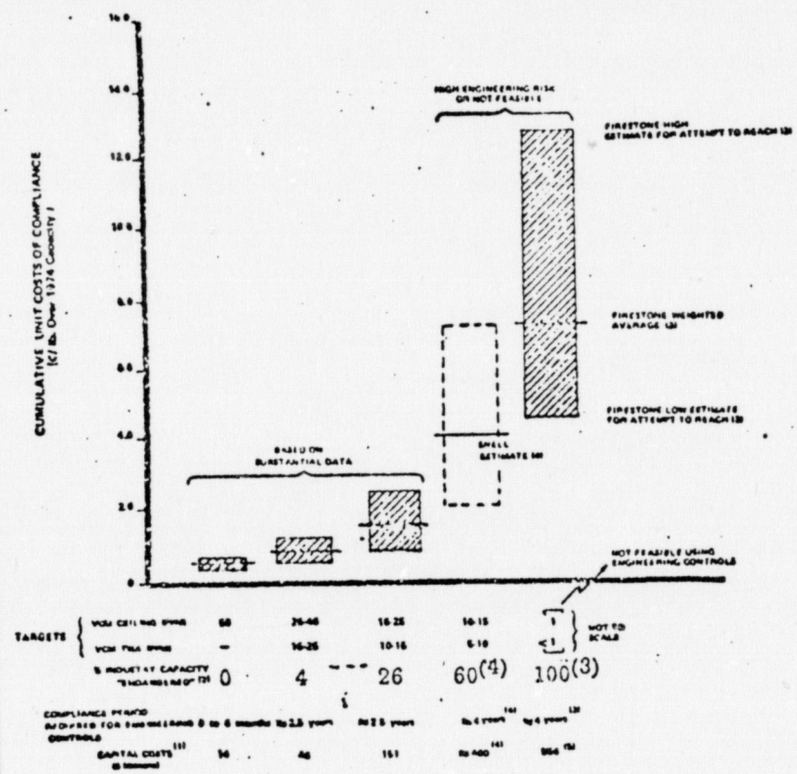
The table indicates the rapid rise in costs associated with attempting to reach the technologically infeasible "no detectable" levels beyond the 10 ppm ceiling and 2 - 5 ppm TWA target level.

Exhibit VI-1, on the following page, presents a similar discussion for the PVC industry.

Exhibit VI-1
USCOLFRMA

PVC INDUSTRY CLAIMED ANNUAL COSTS TO ACHIEVE VCM TARGET LEVELS AND SUSTAIN 1974 CAPACITY (1)

## ECONOMIC IMPACT CRITERIA




### PLANTS LIKELY TO BE MOST "ENDANGERED"(2)

- Highest compliance costs
- Plant located in cold climate
- Old plant
- Small plant
- Small reactors
- Copolymer, emulsion or latex resin production (High free monomer)
- Small company
- Merchant sales
- Slackening demand

### PLANTS LIKELY TO BE LEAST "ENDANGERED"(2)

- Lowest compliance costs
- Plant located in warm climate
- Modern plant with automation
- Large reactors
- Bulk or suspension resin production
- Large company
- Large plant
- Captive use of PVC
- Highly disciplined plant personnel

NOTES:
(1) ESTIMATES INCLUDE COSTS OF ENGINEERING CONTROLS, PERSONAL PROTECTIVE AND MONITORING EQUIPMENT AS WELL AS COSTS DUE TO PRODUCTIVITY LOSSES
(2) ENDANGERED=MANAGEMENT WILL SERIOUSLY CONSIDER A PLANT SHUTDOWN
(3) FIRESTONE PROVIDED COST ESTIMATES RELATED TO "NO DETECTABLE" VCM LEVEL FOR AN ATTEMPT PRIMARILY BASED ON ENGINEERING CONTROLS, CONCLUDING INFEASIBILITY AND INDICATING THAT FIRESTONE PLANTS WOULD BE ALSO "ENDANGERED"
(4) SHELL ESTIMATE BASED ON INTERPOLATION OF INDUSTRY DATA AND AUGEMENTAL ASSESSMENT OF THE ECONOMIC IMPACT CRITERIA ABOVE
(5) SHELL ORDER OF MAGNITUDE PROJECTION FOR THE INDUSTRY BASED ON FIRESTONE DATA WITH ITS LIMITATIONS

SOURCE: INDUSTRY INTERVIEWS, HEARING RECORDS AND SHELL ESTIMATES IN CHAPTER FIVE

- For the VCM industry, the engineering control steps for OSHA compliance are significantly the same as those potentially used for air pollution control. Therefore, appreciable air pollution control costs are automatically accounted for by OSHA compliance.

- For the PVC industry, engineering control steps from the 50 ppm VCM ceiling level to the 15 - 25 ppm ceiling with 10 - 15 ppm TWA primarily address OSHA compliance, but significant air pollution control benefits are gained, especially at lower levels.

3. AREA MONITORING, PARTICULARLY IN PVC PLANTS IS RECOMMENDED TO OSHA AS A COMPLIANCE REQUIREMENT REGARDLESS OF THE TARGET LEVEL SELECTED BY OSHA

- Automatic Sequential Monitoring Systems (ASMS) can serve as a long term data collection system for an entire plant.

  - The ASMS can analyze an air sample from a particular point in the plant in 1 to 3 minutes with potential for at least 10 point monitoring.

  - The ASMS can be used to provide correlation with personnel monitoring data of actual worker exposure. In addition, it can be used to provide a permanent record of VCM levels, provide alarms in case of exceeding ceiling values, serve as a means to initially identify the general sources of VCM releases, and to monitor progress in complying with OSHA requirements.

  - A system installed in the polymerization building can provide warning to work personnel in that area if VCM levels have gone above ceiling levels.

  - Response to alarm can be standardized. These steps could include donning of personal protective equipment, investigation using leak detectors, isolating the point of VCM release and corrective maintenance.

4. IT IS RECOMMENDED THAT OSHA ESTABLISH PHASED REQUIREMENTS FOR REACHING VCM TARGET LEVELS TO ALLOW THE COLLECTION OF ADDITIONAL VCM MONITORING DATA TO FULLY ASSESS THE EFFICIENCY OF THE CORRECTIVE STEPS, SUBJECT TO REVIEW IN LIGHT OF CURRENT MEDICAL FINDINGS, AND AS THEY BECOME AVAILABLE

- The currently available data base particularly for VCM monitoring, is relatively small. In addition, the technology required for compliance with the lower VCM levels is not yet proven. Consequently, considerable risks exist as to the efficacy of engineering controls even for levels other than "no detectable", which is not technologically feasible.

- A phased compliance plan would allow for the assessment of the efficiency of corrective steps already taken by industry. In any event, significant lead times exist for hardware required for engineering controls.

- The phased compliance plan should be reviewed in light of current and emerging medical findings.

- A possible result of a phased compliance plan would be to spread the costs of compliance over periods of time. This may be desirable considering that the VCM and PVC price impacts may be of the same order of magnitude as the price results of the "energy crisis".

- Developmental efforts should be encouraged to improve techniques in personal protective devices, monitoring systems, and residual monomer reductions.

* * * * *

**The Appendices supporting the report follow in a separate volume.**

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September 16, 1974

Mr. Michael Pickens
Attn: OSH Docket-36
Office of Standards and
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Occupational Safety and
Health Administration
U.S. Department of Labor
1726 M Street, N.W.
Washington, D.C. 20210

Re: In The Matter Of: PROPOSED PERMANENT STANDARD FOR OCCUPATIONAL EXPOSURE TO VINYL CHLORIDE

Dear Mr. Pickens:

On behalf of our client, The Society of the Plastics Industry, Inc. (SPI)1/, we are herewith transmitting the data about respiratory protection requirements that you requested. We would assume that these data will be incorporated as a part of the official Record in the above-referenced matter.

This submission is in response to your request for estimates of the percentage of time and numbers of employees who would require respiratory protection under

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1/ The interests, composition and extent of participation of SPI in these proceedings is by now well known to the Department of Labor. A complete discussion of the interests of the Society is specifically detailed in its "Post-Hearing Memorandum of The Society of the Plastics Industry, Inc. --Proposed Findings of Fact and Conclusions Supported by the Record", dated August 23, 1974.

the SPI proposal 2/ for occupational exposure to vinyl chloride.

In reviewing the data contained herein, it must be remembered that the SPI proposal assumes the development and implementation of new technology. It, therefore, represents the best estimates of what a majority of the industry believes it will be able feasibly to accomplish during the next two years. Until new engineering controls are installed and operating, it is not possible to do more than estimate what workplace concentration of vinyl chloride will be achieved, what excursions may be encountered and, therefore, how frequently respiratory protection will be required.

The data contained herein was gathered from each company, collated and submitted as expeditiously as possible. As to the presentation of this information, the tabulation and summary show that the several companies reported information in a variety of modes. Some presented breakdowns and others lumped their totals for each plant together so that the data are stated as weighted averages. From these itemized and integrated reports, a coded table of

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2/ The SPI recommendation for polyvinyl chloride manufacturing operations is that in October, 1974 vinyl chloride should be controlled so that workers are exposed to no more than a 25 ppm 8 hour time weighted average (TWA) nor to more than a 40 ppm ceiling without requiring respiratory protection. In October, 1975, the ceiling value would be reduced to 25 ppm. In October, 1976, the ceiling value of 25 ppm would remain and a 10 ppm 8 hour TWA would be added. In vinyl chloride monomer manufacturing operations, the SPI recommendation is that in October, 1974 occupational exposure should be limited to a 25 ppm ceiling and a 10 ppm 8 hour TWA. In October, 1975, these values would be reduced to a 10 ppm ceiling and 5 ppm 8 hour TWA, respectively.

raw data has been prepared. 3/ These data have been organized to show both the number and percentage of employees requiring respiratory protection by percent of time (Table I). Not apparent from these figures is the fact that some job categories (e.g. tank car loading) require respiratory protection as much as 100% of the time as a work practice. This is not reflected in the crude figures because individual employees do not perform such operations 100% of the time. The wide range of the figures presented illustrates the diverse nature of the industry and that even under the industry proposal considerable use of respiratory protection for workers will be necessary to achieve compliance.

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3/ The average percent time values (average percent of time requiring respiratory protection) shown for those companies that reported breakdowns were arrived at by use of the following formula:

$$\bar{X} = \frac{\Sigma\ XiNi}{\Sigma\ Ni}$$

Where: Xi is the "% of time in respirators" for each group of employees, and
Ni is the "number of employees" in each group.

Each "percent of workers" shown in the tabulation (Colum 4) was multiplied by the "percent time in respirators (Column 5). The sum of these products was divided by the sum of the percent workers. The result was reported as the average percentage of time requiring respiratory protection.

As with our previous submissions in this matter, if you or anyone else receiving copies hereof have any questions as to this information, please do not hesitate to contact us.

Respectfully submitted,

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

By: Jerome H. Heckman /ds

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Enclosures

cc: Mr. Julius Jimeno
Dr. Daniel P. Boyd
Dr. Donald Lassiter
Mr. Eugene Regad, Jr.

## PVC Production

| Number | 1974 Total Workers Potentially Exposed | 1974 Respiratory Protection Required: Number Workers | 1974 Respiratory Protection Required: Percent Workers | 1974 Respiratory Protection Required: Percent Time | | 1975 Total Workers Potentially Exposed | 1975 Respiratory Protection Required: Number Workers | 1975 Respiratory Protection Required: Percent Workers | 1975 Respiratory Protection Required: Percent Time | | 1976 Total Workers Potentially Exposed | 1976 Respiratory Protection Required: Number Workers | 1976 Respiratory Protection Required: Percent Workers | 1976 Respiratory Protection Required: Percent Time | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 208 | 60 | 29 | 22 | | 223 | 68 | 30 | 38 | | 223 | 78 | 35 | 63 | |
| 2 | 360 | 241 | 67 | 25 | | 360 | 266 | 74 | 35 | | 360 | 266 | 74 | 20 | |
| 3 | 107 | 36 | 34 | 17 | | 107 | 56 | 52 | 23 | | 78 | 26 | 33 | 12 | |
| 4 | 123 | 46 | 37 | 25 | | 123 | 50 | 41 | 25 | | 123 | 50 | 41 | 25 | |
| 5 | 136 | 56 | 41 | 25 | | 136 | 56 | 41 | 50 | | 136 | 56 | 41 | 50 | |
| | | 4 | 3 | 13 | | | 4 | 3 | 25 | | | 4 | 3 | 25 | |
| | | 42 | 31 | 1 | | | 42 | 31 | 1 | | | 42 | 31 | 1 | |
| | | 102 | 75 | 15 | avg. | | 102 | 75 | 29 | avg. | | 102 | 75 | 29 | a |
| 6 | 203 | 9 | 4 | 15 | | 203 | 3 | 1 | 15 | | 203 | 2 | 1 | 10 | |
| | | 3 | 1 | 1 | | | 1 | 0.5 | 1 | | | 1 | 0.5 | 1 | |
| | | 12 | 6 | 12 | avg | | 4 | 2 | 12 | avg. | | 3 | 1.5 | 7 | a. |
| 7 | 66 | 35 | 53 | 23 | | 81 | 39 | 48 | 36 | | 81 | 47 | 58 | 7 | |
| 8 | 28 | 10 | 36 | 19 | | 28 | 10 | 36 | 38 | | 28 | 10 | 36 | 38 | |
| | | 10 | 36 | 6 | | | 10 | 36 | 13 | | | 10 | 36 | 1 | |
| | | 20 | 71 | 13 | avg. | | 20 | 71 | 26 | avg. | | 20 | 71 | 26 | a |

PVC Production

| Number | 1974 | | | | 1975 | | | | 1976 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Total Workers Potentially Exposed | Respiratory Protection Required | | | Total Workers Potentially Exposed | Respiratory Protection Required | | | Total Workers Potentially Exposed | Respiratory Protection Required | | |
| | | Number Workers | Percent Workers | Percent Time | | Number Workers | Percent Workers | Percent Time | | Number Workers | Percent Workers | Percent Time |
| 9 | 98 | 16 | 16 | 56 | 98 | 4 | 4 | 20 | 98 | 4 | 4 | 10 |
| | | 4 | 4 | 40 | | 8 | 8 | 10 | | 4 | 4 | 5 |
| | | 4 | 4 | 30 | | 4 | 4 | 2 | | 8 | 8 | 8 avg. |
| | | 4 | 4 | 15 | | 16 | 16 | 11 avg. | | | | |
| | | 12 | 12 | 10 | | | | | | | | |
| | | 12 | 12 | 5 | | | | | | | | |
| | | 4 | 4 | 2 | | | | | | | | |
| | | 56 | 57 | 23 avg. | | | | | | | | |
| 10 | 158 | 117 | 74 | 10 | 155 | 115 | 74 | 20.5 | 155 | 115 | 74 | 16 |
| 11 | 120 | 20 | 17 | 9 | 120 | 14 | 12 | 9 | 120 | 14 | 12 | 9 |
| 12 | 140 | 54 | 39 | 25 | 140 | 100 | 71 | 30 | 140 | 100 | 71 | 30 |
| 13 | 106 | 10 | 9 | 50 | 106 | 10 | 9 | 60 | 106 | 10 | 9 | 60 |
| | | 10 | 9 | 10 | | 10 | 9 | 20 | | 10 | 9 | 20 |
| | | 40 | 38 | 5 | | 40 | 38 | 10 | | 40 | 38 | 10 |
| | | 38 | 36 | 1 | | 38 | 36 | 2 | | 38 | 36 | 2 |
| | | 98 | 92 | 9 avg. | | 98 | 92 | 13 avg. | | 98 | 92 | 13 |
| 14 | 146 | 24 | 16 | 50 | 146 | 24 | 16 | 50 | 146 | 4 | 3 | 25 |
| | | 38 | 26 | 2.5 | | 38 | 26 | 2.5 | | 38 | 26 | 1. |
| | | 62 | 42 | 21 avg | | 62 | 42 | 21 avg. | | 42 | 29 | 40 |
| 15 | 150 | 45 | 30 | 5 | 150 | 52 | 35 | 10 | 150 | 52 | 35 | 10 |

# PVC Production

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| Number | 1974 Total Workers Potentially Exposed | 1974 Respiratory Protection Required: Number Workers | 1974 Respiratory Protection Required: Percent Workers | 1974 Respiratory Protection Required: Percent Time | 1975 Total Workers Potentially Exposed | 1975 Respiratory Protection Required: Number Workers | 1975 Respiratory Protection Required: Percent Workers | 1975 Respiratory Protection Required: Percent Time | 1976 Total Workers Potentially Exposed | 1976 Respiratory Protection Required: Number Workers | 1976 Respiratory Protection Required: Percent Workers | 1976 Respiratory Protection Required: Percent Time |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 16 | 202 | 93 | 46 | 12 | 202 | 93 | 46 | 10 | 202 | 93 | 46 | 8 |
| 17 | – | – | 100 | 12 | 1 | – | 100 | 5 | 1 | – | 100 | <5 |
| 18 | 585 | 380 | 65 | 3 | 609 | 396 | 65 | 6 | 665 | 432 | 65 | 10 |
| 9 | 70 | 4 | 6 | 32 | 70 | 4 | 6 | 33 | 70 | 4 | 6 | 32 |
| | | 16 | 23 | 26 | | 16 | 23 | 17 | | 5 | 7 | 17 |
| | | 5 | 7 | 17 | | 12 | 17 | 13 | | 16 | 23 | 13 |
| | | 12 | 17 | 8.5 | | 4 | 6 | 12 | | 12 | 17 | 8.5 |
| | | 4 | 6 | 8 | | 13 | 19 | 10.5 | | 4 | 6 | 8 |
| | | 4 | 6 | 7.5 | | 4 | 6 | 9 | | 4 | 6 | 7.5 |
| | | 8 | 11 | 7 | | 5 | 7 | 6 | | 8 | 11 | 7 |
| | | 5 | 7 | 5 | | 12 | 17 | 1 | | 5 | 7 | 5 |
| | | 12 | 17 | 1 | | 70 | 100 | 12 avg. | | 12 | 17 | 1 |
| | | 70 | 100 | 13 avg. | | | | | | 70 | 100 | 10a |
| 0 | 110 | 9 | 8 | 25 | 110 | 9 | 8 | 25 | 110 | 9 | 8 | 25 |
| 1 | 324 | 16 | 5 | 50 | 324 | 16 | 5 | 50 | 324 | 8 | 2 | 25 |
| | | 107 | 33 | 20 | | 107 | 33 | 20 | | 107 | 33 | 15 |
| | | 123 | 38 | 24 avg. | | 123 | 38 | 24 avg. | | 115 | 35 | 16 |
| 2 | 350 | 158 | 45 | 16 | 350 | 182 | 52 | 33 | 350 | 182 | 52 | 33 |
| 3 | 51 | 36 | 70 | 2.5 | 50 | 20 | 40 | 3.5 | 50 | 20 | 40 | 2 |

## PVC Production

2155

| Number | 1974 Total Workers Potentially Exposed | 1974 Respiratory Protection Required: Number Workers | 1974 Respiratory Protection Required: Percent Workers | 1974 Respiratory Protection Required: Percent Time | | 1975 Total Workers Potentially Exposed | 1975 Respiratory Protection Required: Number Workers | 1975 Respiratory Protection Required: Percent Workers | 1975 Respiratory Protection Required: Percent Time | | 1976 Total Workers Potentially Exposed | 1976 Respiratory Protection Required: Number Workers | 1976 Respiratory Protection Required: Percent Workers | 1976 Respiratory Protection Required: Percent Time |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 4 | 72 | 8 | 11 | 34 | | 72 | 8 | 11 | 40 | | 72 | 8 | 11 | 34 |
| | | 9 | 13 | 20.5 | | | 9 | 13 | 27.5 | | | 9 | 13 | 20. |
| | | 18 | 25 | 16 | | | 18 | 25 | 24 | | | 18 | 25 | 16 |
| | | 11 | 15 | 14 | | | 16 | 22 | 20 | | | 11 | 15 | 14 |
| | | 5 | 7 | 12 | | | 12 | 17 | 19 | | | 5 | 7 | 12 |
| | | 12 | 17 | 11 | | | 9 | 13 | 10 | | | 12 | 17 | 11 |
| | | 4 | 6 | 9 | | | 72 | 100 | 23 | avg. | | 4 | 6 | 9 |
| | | 5 | 7 | 6 | | | | | | | | 5 | 7 | 6 |
| | | 72 | 100 | 16 | avg. | | | | | | | 72 | 100 | 16. |
| 5 | 603 | 603 | 100 | 10.5 | | 603 | 603 | 100 | 12 | | 603 | 603 | 100 | 17 |
| 6 | 60 | 31 | 52 | 28 | | 60 | 31 | 52 | 37 | | 60 | 31 | 52 | 44 |
| | | 19 | 31 | 6 | | | 19 | 31 | 11 | | | 19 | 31 | 11 |
| | | 50 | 83 | 20 | avg. | | 50 | 83 | 27 | avg. | | 50 | 83 | 31. |
| 7 | 367 | 219 | 60 | 10 | | 367 | 234 | 64 | 15 | | 367 | 234 | 64 | 15 |
| MMARY | 4943 | 2817 | 57 | | | 4993 | 2914 | 58 | | | 5020 | 2901 | 58 | |

# VCM Production

3333

| Report Number | 1974 Total Workers Potentially Exposed | 1974 Respiratory Protection Required: Number Workers | 1974 Respiratory Protection Required: Percent Workers | 1974 Respiratory Protection Required: Percent Time | | 1975 Total Workers Potentially Exposed | 1975 Respiratory Protection Required: Number Workers | 1975 Respiratory Protection Required: Percent Workers | 1975 Respiratory Protection Required: Percent Time | |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 109 | 75 | 69 | 5 | | 109 | 75 | 69 | 2.5 | |
| 2 | 126 | 20 | 16 | 2 | | 126 | 20 | 16 | 2 | |
| | | 106 | 84 | 1 | | | 106 | 84 | 1 | |
| | | 126 | 100 | 1 | avg. | | 126 | 100 | 1 | avg. |
| 3 | 193 | 27 | 14 | 2.5 | | 193 | 27 | 14 | 4 | |
| 4 | 30 | 0 | 0 | 0 | | 30 | 0 | 0 | 0 | |
| 5 | 76 | 15 | 20 | 2 | | 76 | 15 | 20 | 2 | |
| | | 61 | 80 | 1 | | | 61 | 80 | 1 | |
| | | 76 | 100 | 1 | avg | | 76 | 100 | 1 | avg. |
| 6 | 60 | 20 | 33 | 20 | | 60 | 0 | 0 | 0 | |
| 7 | 15 | 15 | 100 | 10 | | 15 | 15 | 100 | 40 | |
| 8 | 20 | 7 | 35 | 3 | | 20 | 7 | 35 | 3 | |
| | | 13 | 65 | 1 | | | 13 | 65 | 1 | |
| | | 20 | 100 | 2 | avg. | | 20 | 100 | 2 | avg. |
| 9 | 30 | 3 | 10 | 10 | | 30 | 3 | 10 | 10 | |
| 10 | 123 | 123 | 100 | 7 | | 128 | 128 | 100 | 11 | |
| 11 | 81 | 81 | 100 | 12.5 | | 81 | 81 | 100 | 20 | |
| summary | 863 | 566 | 65.6 | | | 868 | 551 | 63.5 | | |

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TABLE I

Number and Percent of Employees
Requiring Respiratory Protection

A. PVC Production

| Year | Number Workers Potentially Exposed | Percent Time Requiring Respiratory Protection | | | | | |
|---|---|---|---|---|---|---|---|
| | | 0 | 1-19 | 20-39 | 40-59 | 60-79 | 80-99 |
| 1974 | 4943 | 2126 | 2060 | 687 | 70 | --- | --- |
| | 100% | 43.0% | 41.7% | 13.9% | 1.4% | --- | --- |
| 1975 | 4993 | 2079 | 1702 | 1098 | 104 | 10 | --- |
| | 100% | 41.6% | 34.1% | 22.0% | 2.1% | 0.2% | --- |
| 1976 | 5020 | 2119 | 2015 | 664 | 87 | 135 | --- |
| | 100% | 42.2% | 40.1% | 13.2% | 1.7% | 2.7% | --- |

B. VCM Production

| | | 0 | 1-9 | 10-19 | 20-29 | 30-39 | 40-49 |
|---|---|---|---|---|---|---|---|
| 1974 | 863 | 297 | 447 | 99 | 20 | --- | --- |
| | 100% | 34.4% | 51.8% | 11.5% | 2.3% | --- | --- |
| 1975 | 868 | 317 | 327 | 128 | 81 | --- | 15 |
| | 100% | 36.5% | 37.7% | 14.8% | 9.3% | --- | 1.7% |

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# AN EVALUATION OF ORGANIC VAPOR RESPIRATOR CARTRIDGES AND CANISTERS AGAINST VINYL CHLORIDE

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and

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Center for Disease Control
National Institute for Occupational Safety and Health
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Cincinnati, Ohio 45202

July, 1974

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## ABSTRACT

The service lives of four types of approved organic vapor respirator cartridges and four types of approved front or back mounted organic vapor gas mask canisters were determined relative to several concentrations of vinyl chloride. Various mixtures of vinyl chloride gas and air were passed through the cartridges and canisters and the downstream concentration was monitored until breakthrough occurred.

The effect of concentration on breakthrough time conformed to adsorption theory.

Brief investigations indicated service life increased at low humidities and decreased at high humidities.

Recommendations are made concerning the use of organic vapor respirator cartridges and gas mask canisters in atmospheres containing vinyl chloride gas, based on expected service life and facepiece leakage.

## INTRODUCTION

Vinyl chloride is a synthetic chemical made by oxychlorination of ethylene or by hydrochlorination of acetylene. It is used in the manufacture of containers, wrapping film, electrical insulation, pipe, conduit, and a variety of other products.

In January of 1974, it became known to the National Institute for Occupational Safety and Health(NIOSH) and the Occupational Safety and Health Administration(OSHA) that several employees of the B.F. Goodrich Chemical Company had died from a rare form of liver cancer (angiosarcoma) that may have been occupationally related.

Information presented at a fact-finding hearing to determine the hazards of polyvinyl chloride and vinyl chloride, held by OSHA on February 15, 1974, showed that tumors were produced in animals at concentrations as low as 250 ppm. On the basis of this information an Emergency Temporary Standard was promulgated by OSHA on April 5, 1974. This standard reduced allowable ceiling exposure from 500 ppm to 50 ppm.

On April 15, 1974 information was presented to representatives of OSHA, NIOSH, and EPA by Industrial Bio-Test Laboratories which indicate that angiosarcomas were produced in animals at concentrations of 50 ppm. On this basis, a Proposed Permanent Standard on vinyl chloride was published by OSHA in the Federal Register on May 10, 1974, proposing no detectable level of employee exposure as determined by a method capable of detecting 1 ppm vinyl chloride.

In both the Emergency Temporary Standard and the Proposed Permanent Standard, air-supplied respirators and self-contained breathing apparatus are specified for respiratory protection in atmospheres greater than the ceiling limit.(1,2)

Only limited testing has been done to evaluate organic vapor cartridges and canisters against vinyl chloride. In a study by Lawrence Livermore Labs (A.E.C.) cartridges were evaluated against various classes of organic vapors at concentrations of 1000 ppm. One of these vapors was vinyl chloride. Cartridge life (10% breakthrough) in this test was less than 10 minutes.(3) A 10% breakthrough time occurs when cartridge or canister penetration concentration reaches 10% of the ambient concentration.

In discussing service life of charcoal cartridges or canisters, limitations of facepiece fit must be recognized. Protection factors for various types of respirators are discussed by Hyatt, et al in a paper presented at the 16th Annual Meeting of the Health Physics Society in New York City, July 12 -

16, 1971.[4] A protection factor is defined as the ratio of ambient contamination to contaminant levels within a facepiece. Protection factors for half mask respirators and full-facepiece gas masks are 10 and 100 respectively. Thus, based on fit alone, half mask organic vapor respirators and full-facepiece gas masks could be used in contaminant concentrations of 10 and 100 times the substance ceiling value respectively.

The purpose of this testing program was to gain information on service lives (time a cartridge or canister may be used before breakthrough occurs) of organic vapor cartridges and canisters in concentration ranges consistent with both the Emergency Temporary Standard, the Proposed Permanent Standard for vinyl chloride and established protection factors for half mask organic vapor respirators and full-facepiece gas masks.

In this program, four types of NIOSH/Bureau of Mines approved organic vapor respirator cartridges and four types of NIOSH/BM approved front or back mounted organic vapor gas mask canisters were tested. The weights of charcoal in each of these devices are shown in Table 1. Other than the weight of charcoal in each cartridge or canister, adsorption characteristics were unknown.

Adsorption theory predicts that charcoal is more efficient at higher contaminant vapor pressures. If the equation for service life of various cartridges and canisters versus concentration can be determined for vinyl chloride, then cartridge or canister life can be predicted at concentrations other than test concentrations. An effort was made to establish this relationship for vinyl chloride.

The humidity of ambient air can affect the adsorption capacity of charcoal. This effect was also briefly investigated in relation to vinyl chloride.

## TEST SETUP

### Generation

The generation system consisted of an air preconditioning subsystem and a vinyl chloride metering subsystem. A schematic diagram of the system is shown in Figure 1. Air was first passed through a solution of 20% NaOH to remove $CO_2$. The air stream was then divided and passed through either water or concentrated sulfuric acid to condition the air to the desired relative humidity. Air flow was monitored with a dry test meter prior to being mixed with vinyl chloride.

Vinyl chloride gas was taken from one of four tanks of vinyl chloride in nitrogen (0.1%, 1%, 10%, or 20%). The flow

rate from the appropriate tank was controlled by means of a metering valve and calibrated orifice. The vinyl chloride was then mixed to the desired concentration with the preconditioned air and delivered to the cartridge or canister.

### Detection

A Wilks Scientific Miran I variable pathlength infrared analyzer was used to monitor ambient and breakthrough concentrations of vinyl chloride. All analyses were done at the 10.9 micron wavelength adsorption band. No interferences were detected. A cartridge or canister penetration sample was pulled through the 5.5 liter analyzer gas sample cell at the flow rate of 6.5 LPM. Breakthrough times were corrected for the resultant 3-minute lag in response. Bags filled with the ambient concentration were periodically analyzed with a gas chromatograph by the Physical and Chemical Analysis Branch of NIOSH to verify test concentrations. Results agreed well within 10%.

## TESTS PERFORMED

### Preliminary Tests

Preliminary tests were performed on one cartridge type from a single batch to determine the effects of ambient relative humidity on breakthrough time. These tests were run at 600 ppm, 75 $\pm$ 5°F. Flow rates were based on a moderately heavy work rate of approximately 930 Kg-m/min. This corresponds to a breathing rate of 60 LPM. Cartridges were tested at 30 LPM since they are normally used in pairs. Cartridges were tested at 25, 50, and 85% relative humidity. Tests were run until 50% breakthrough occurred. Breakthrough times for initial, 10% and 50% cartridge penetration were recorded.

### Cartridge Tests

All cartridges in this phase were tested singly at a constant flow rate of 30 LPM. The test atmosphere was controlled at 75 + 5°F, 50 + 5% RH. Test concentrations of vinyl chloride were 250, 500, 750 ppm. At least three cartridges of each of four types were tested at each concentration. In certain circumstances additional tests were run to correlate results obtained from cartridges from different boxes. Also, two cartridges of each of the four types were tested at ambient concentration of 50 ppm. In the tests run at 50 ppm, the test was terminated at 10% breakthrough. In all other tests, cartridges were run until 50% breakthrough occurred. Where possible, initial, 10% and 50% breakthrough times were recorded.

## Canister Tests

All canisters were tested at a constant flow rate of 60 LPM. Again, the test atmosphere was kept at 75 ± 5°F, 50 ± 5% RH. At least two canisters of each of four types were tested at each concentration. Concentrations used were 100, 1000, and 5000 ppm. Canisters were run until 10% breakthrough occurred. Initial and 10% breakthrough times were recorded.

## TEST RESULTS

During preliminary testing, a large amount of breakthrough time variability was noticed in cartridges of the same type but from different boxes. These data are shown in Table 2. Variability was also noticed between boxes throughout the testing program, though to a lesser degree.

Figure 2 shows the results of tests to determine the effect of relative humidity on service life of cartridges. From this figure it appears that service life is inversely proportional to ambient relative humidity. A service life decrease of about 16% was seen from tests at 50% RH to tests at 85% RH.

Data from cartridge service life tests is shown in Table 3. These data are shown graphically in Figures 3, 4, 5, and 6. Adsorption theory predicts that charcoal becomes more efficient at higher contaminant concentrations. The graphs of cartridge service life data demonstrate this phenomenon.

It was found that an exponential decay curve was the most appropriate model for service life data. This relationship is defined as:

$$X = Ae^{-BY}$$

where X is vinyl chloride concentration in ppm and Y is 10% breakthrough time in minutes. When the natural logarithm (log e) of the concentration is taken, the relationship becomes:

$$Y = (1/B) \log_e A - (1/B) \log_e X$$

This is the equation of a straight line on semilog graph paper.

Using this model, data for cartridges and canisters were found to be very consistent. Correlation coefficients ranged from 0.981 to 0.994.

The regression equations for each make of cartridge and canister are shown on Table 5 as well as correlation coefficients and equations for 95% tolerance limits.

Statistical analysis was not performed on initial breakthrough times because of the qualitative nature of the data. The point at which vinyl chloride could be first detected (initial breakthrough) depends not only on instrument settings and baseline drift but on personal judgement as well. However, initial breakthrough times for cartridges were typically 33% lower than the 10% breakthrough times.

Data from canister service life tests are shown in tabular form in Table 4 and in graphical form in Figures 7, 8, 9 and 10. For canisters initial breakthrough times recorded were typically 18% lower than the 10% breakthrough times.

## CONCLUSIONS

Conventional activated charcoal of the type used in respirator cartridges and canisters has a very low adsorption capacity for vinyl chloride. This is demonstrated by the short service life of respirator organic vapor cartridges. In tests run at 50 ppm, 50% relative humidity, the lower 95% confidence level for 10% breakthrough time is 40 minutes. A minimum service time must also take into account the time between initial and 10% breakthrough (approximately 33%) and decreased service life due to high humidities (approximately 16%). These factors produce a minimum expected service life for cartridges of 20 minutes.

In canister tests at 100 ppm, 50% relative humidity, the lower 95% confidence level for 10% breakthrough time is 160 minutes. Considering factors for the time difference between initial and 10% breakthrough (18% of the 10% breakthrough time) and decreased in service life due to increased humidity (16%), a minimum service life of 100 minutes can be expected.

Organic vapor respirator cartridges have sufficient life for 20 minutes service at concentrations less than 50 ppm. Organic vapor front or back mounted gas mask canisters have sufficient life for 100 minutes service at concentrations less than 100 ppm.

Protection factors for half-mask organic vapor respirators and for full-facepiece organic vapor gas masks are 10 and 100 respectively. Theoretically, therefore, these devices could be used in contaminant concentrations up to 10 and 100 times

the exposure limit if facepiece fit were the only consideration. With a 50 ppm ceiling exposure limit, an organic vapor half-mask respirator could be used in concentrations up to 500 ppm and an organic vapor full-facepiece gas mask up to 5000 ppm, without regard to service life.

However, when considering no detectable level of exposure as an exposure limit, both half-mask organic vapor respirators and full-facepiece gas masks would not provide adequate protection.

Another important point of interest when considering use of half-mask organic vapor respirators and full-facepiece gas masks are the warning properties of the contaminant. Vinyl chloride has an odor threshold of approximately 500 to 1000 ppm. A worker wearing these types of devices would have no indication of whether he was being adequately protected in atmospheres with low concentrations of vinyl chloride.

## RECOMMENDATIONS

During the course of this testing program, the need for improvement in respirator performance has been demonstrated. Carbon tetrachloride is specified in 30 CFR 11 as the ambient contaminant in the approval of organic vapor cartridges and canisters.[5] Of the 121 solvent vapors and gases tested by Nelson,[3] 51 have lower 10% breakthrough times than carbon tetrachloride. No provisions are made in the NIOSH/BM approval labeling scheme for specifying expected service life. Work needs to be done to assure that devices approved are adequate for gases like vinyl chloride and the 50 other more volatile gases and vapors. A scheme should be developed to test devices against various classes of vapors. In this way, life expectancy could be given for a specific contaminant within one of these classes.

Work should be done to determine the effect of various charcoal characteristics (weight, particle size, pore size, base media, activation method, etc.) on adsorption capacity. For a comprehensive approval program to be meaningful, these characteristics should be defined and assurance must be made that they are adequately controlled in the manufacture of approved devices.

Work should be initiated to find or develop more efficient sorbents for substances which show poor adsorption on conventional respirator charcoal.

Another point of value would be to develop a device to be used integrally with respirator cartridges and canisters

which would enable the user to determine if his cartridge or canister has reached breakthrough. Such a device might operate on the same principle as the detector tube.

## SUMMARY

Organic vapor respirator cartridges have sufficient life for 20 minutes service at concentrations less than 50 ppm. Organic vapor front or back mounted gas mask canisters have sufficient life for 100 minutes service at concentrations less than 100 ppm. Facepiece leakage is expected to be 10% for a half mask respirator and 1% for a full-facepiece respirator. A final decision regarding their use against vinyl chloride must be based on the allowable ceiling exposure for vinyl chloride adopted in a permanent standard and expected facepiece leakage.

The approval system for organic vapor respirators and gas masks should be studied and improved in order to assure protection against highly volatile gases and to provide the user with information on service life.

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2. Department of Labor, Occupational Safety and Health Administration. Vinyl Chloride - Proposed Standard, Title 29 Code of Federal Regulations, Part 1910. Federal Register, Vol. 39, No. 92, Friday, May 10, 1974.

3. Nelson, G.O., and C. A. Harder. Respirator Cartridge Efficiency Studies: V. Effect of Solvent Vapor. Lawrence Livermore Laboratories Report Number UCRL 75056, August 30, 1973. Livermore, California.

4. Hyatt, E.C., J. A. Pritchard, and C.P. Richards. Protection Factors for Respirators. Presented at 16th Annual Meeting of the Health Physics Society, New York City, New York, July 12-16, 1974. Los Alamos Scientific Laboratory Document No. LA-DC-12318.

5. Department of the Interior, Bureau of Mines. Respiratory Protective Devices; Tests for Permissibility; Fees; Title 30 Code of Federal Regulations, Part 11. Federal Register, Vol. 37, No. 59, Saturday, March 25, 1972.

Table 1. Cartridge and Canister Charcoal Weights

Cartridges

| Manufacturer | Charcoal Weight (GMS) |
|---|---|
| 1 | 49.7 |
| 2 | 35.7 |
| 3 | 35.0 |
| 4 | 36.1 |

Canisters

| Manufacturer | Charcoal Weight (GMS) |
|---|---|
| 1 | 436.8 |
| 2 | 318.4 |
| 3 | 463.8 |
| 4 | 312.2 |

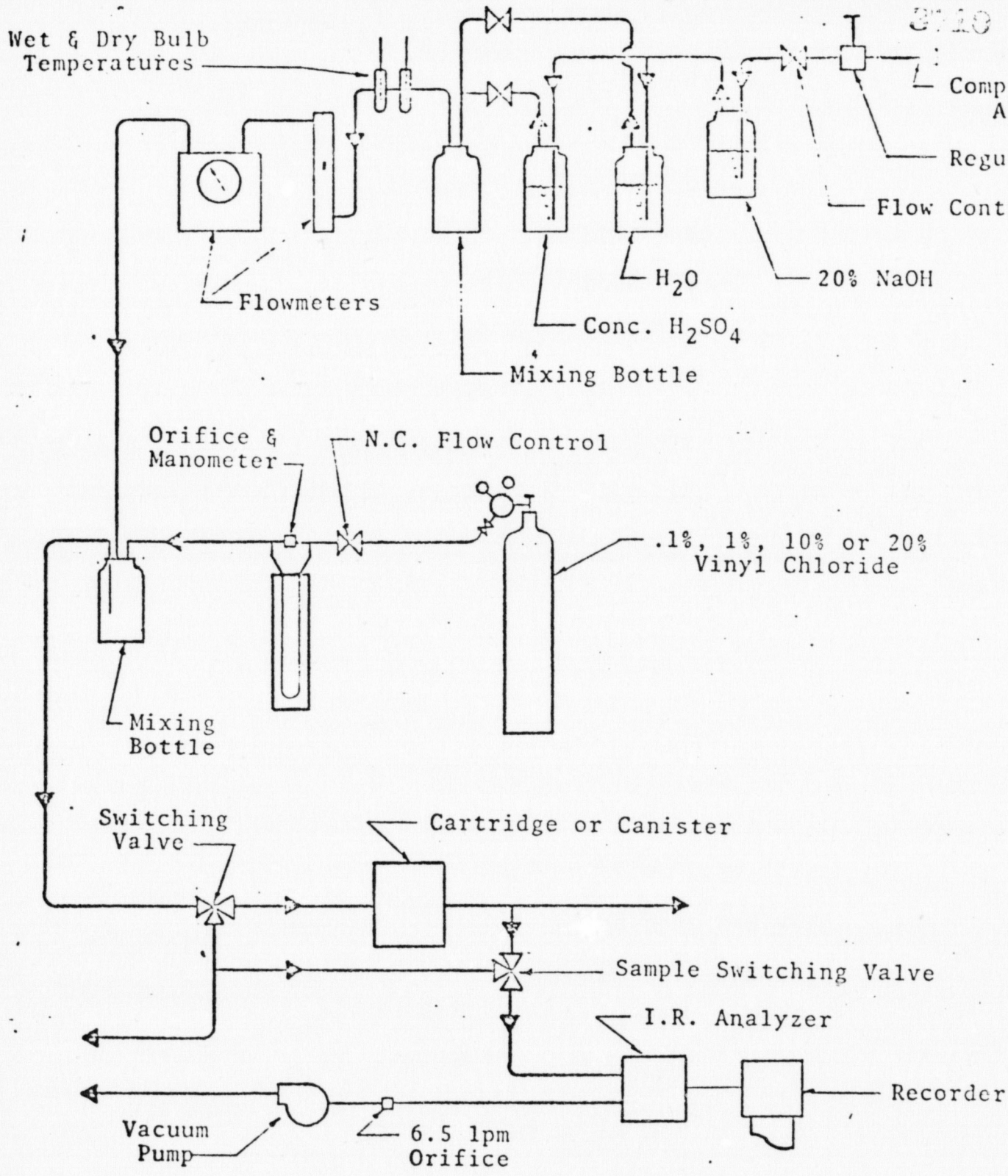



Figure 1. VINYL CHLORIDE CARTRIDGE AND CANISTER TESTING SYSTEM

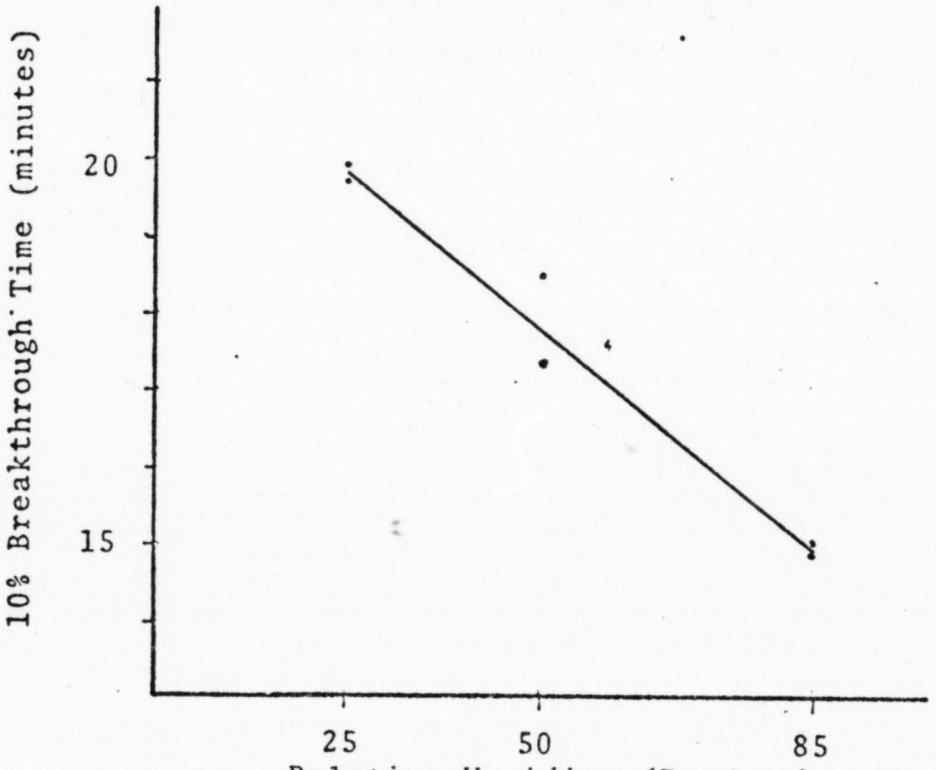
Table 2. Cartridge Variability Between Boxes

| Box Number | Number of Tests | Breakthrough Times (minutes) | | | | | |
|---|---|---|---|---|---|---|---|
| | | Initial | | 10% | | 50% | |
| | | $\bar{x}$ | $\sigma$ | $\bar{x}$ | $\sigma$ | $\bar{x}$ | $\sigma$ |
| 1 | 3 | 4.98 | 0.65 | 9.87 | 0.76 | 15.4 | 0.7 |
| 2 | 5 | 12.1 | 0.47 | 17.24 | 0.77 | 22.15 | 0.71 |

Note: Above tests run at 30 LPM total flow, 500 ppm 50% RH

$\bar{x}$ = mean

$\sigma$ = standard deviation




Note: Tests Run at 600 ppm, 30 lpm Flow Rate

Figure 2. EFFECT OF RELATIVE HUMIDITY ON CARTRIDGE BREAKTHROUGH TIME

Table 3

Cartridge Test Data

| Concentration (ppm) | Manufacturer | Number of Tests | Breakthrough Times (minutes) | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | Initial | | 10% | | 50% | |
| | | | $\bar{x}$ | $\sigma$ | $\bar{x}$ | $\sigma$ | $\bar{x}$ | $\sigma$ |
| 750 | 1 | 3 | 17.27 | 1.17 | 25.28 | 1.16 | 32.63 | 1.33 |
| 750 | 2 | 3 | 9 | 0 | 16.73 | 0.35 | 23.53 | 0.32 |
| 750 | 3 | 3 | 7.2 | 0.26 | 13.37 | 0.32 | 19.72 | 0.94 |
| 750 | 4 | 3 | 10.9 | 0.1 | 16.58 | 0.43 | 22.4 | 0.3 |
| 500 | 1 | 4 | 22.65 | 6.3 | 33 | 4.81 | 42.73 | 4.85 |
| 500 | 2 | 3 | 11.55 | 0.71 | 20.7 | 0.7 | 30.02 | 0.73 |
| 500 | 3 | 5 | 11.42 | 1.18 | 18.6 | 1.71 | 26.66 | 2.01 |
| 500 | 4 | 3 | 13.37 | 0.32 | 10.75 | 1.02 | 26.62 | 1.42 |
| 250 | 1 | 3 | 41.77 | 1.46 | 51.37 | 0.7 | 67.2 | 0.8 |
| 250 | 2 | 3 | 20.27 | 2.12 | 29.7 | 1.03 | 42.93 | 0.91 |
| 250 | 3 | 3 | 21.13 | 2.26 | 28.8 | 2.36 | 41.3 | 2.84 |
| 250 | 4 | 3 | 21.2 | 1.04 | 28.13 | 0.85 | 39.07 | 0.93 |
| 50 | 1 | 2 | 54.38 | 0.53 | 74.06 | 3.45 | - | - |
| 50 | 2 | 2 | 28.13 | 2.65 | 43.5 | 1.06 | - | - |
| 50 | 3 | 2 | 29.25 | 3.18 | 48. | 0 | - | - |
| 50 | 4 | 2 | 32.63 | 2.65 | 48 | 3.18 | - | - |

Note: Above tests run at 30 LPM total flow and 50% RH

Table 4. Canister Test Data

| Concentration ppm | Manufacturer | Number of Tests | Breakthrough Times (Min) | | | |
|---|---|---|---|---|---|---|
| | | | Initial | | 10% | |
| | | | $\bar{x}$ | $\sigma$ | $\bar{x}$ | $\sigma$ |
| 5000 | 1 | 2 | 54.5 | 0.71 | 53.24 | 1.06 |
| 5000 | 2 | 2 | 33 | 1.41 | 43.25 | 1.06 |
| 5000 | 3 | 2 | 31 | 1.41 | 43.0 | 1.41 |
| 5000 | 4 | 2 | 25.5 | 0.71 | 33.0 | 0 |
| 1000 | 1 | 3 | 144.3 | 5.51 | 158.0 | 3.61 |
| 1000 | 2 | 3 | 95.67 | 10.97 | 111.0 | 4.58 |
| 1000 | 3 | 3 | 90.67 | 4.04 | 108.3 | 5.51 |
| 1000 | 4 | 3 | 72.3 | 2.52 | 84 | 2.0 |
| 100 | 1 | 2 | 312 | 0 | 356 | 5.66 |
| 100 | 2 | 2 | 218.5 | 3.54 | 284 | 4.24 |
| 100 | 3 | 2 | 217 | 5.66 | 276.5 | 7.78 |
| 100 | 4 | 2 | 169.5 | 6.36 | 208.5 | 6.36 |

Note: Above tests run at 60 LPM total flow and 50% RH

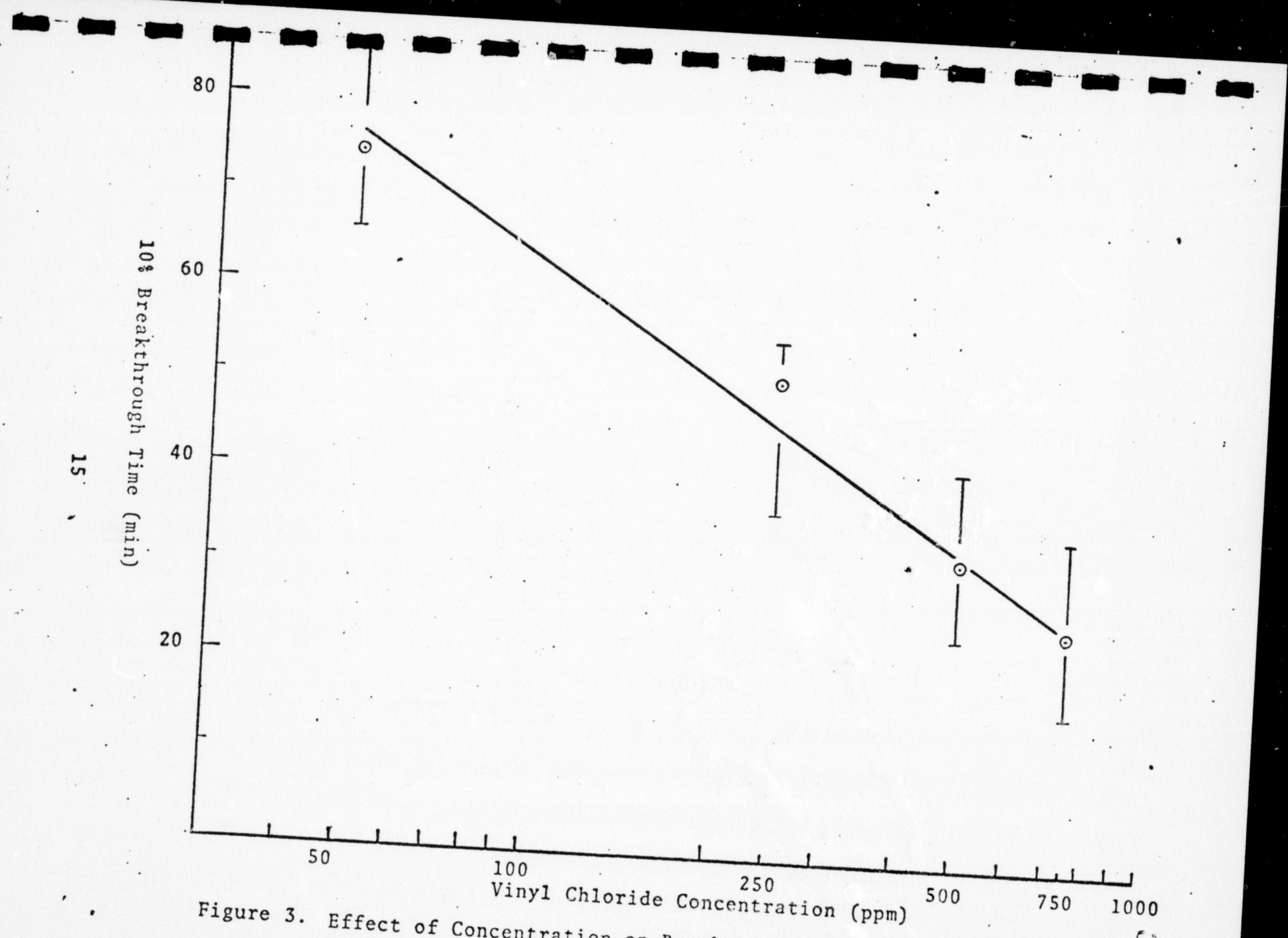



Figure 3. Effect of Concentration on Breakthrough Time - Cartridge Make #1

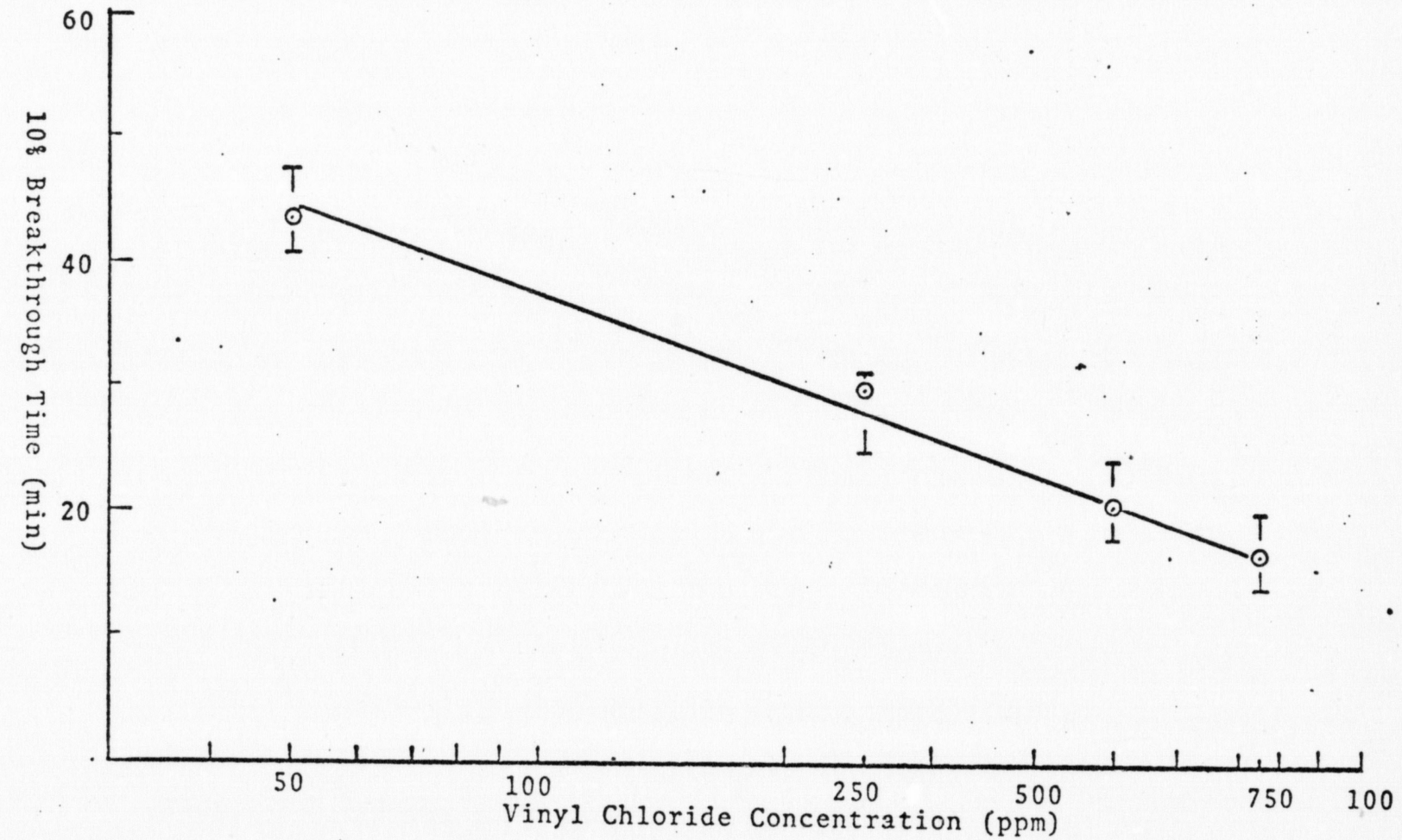



Figure 4. Effect of Concentration on Breakthrough Time
Cartridge Make #2

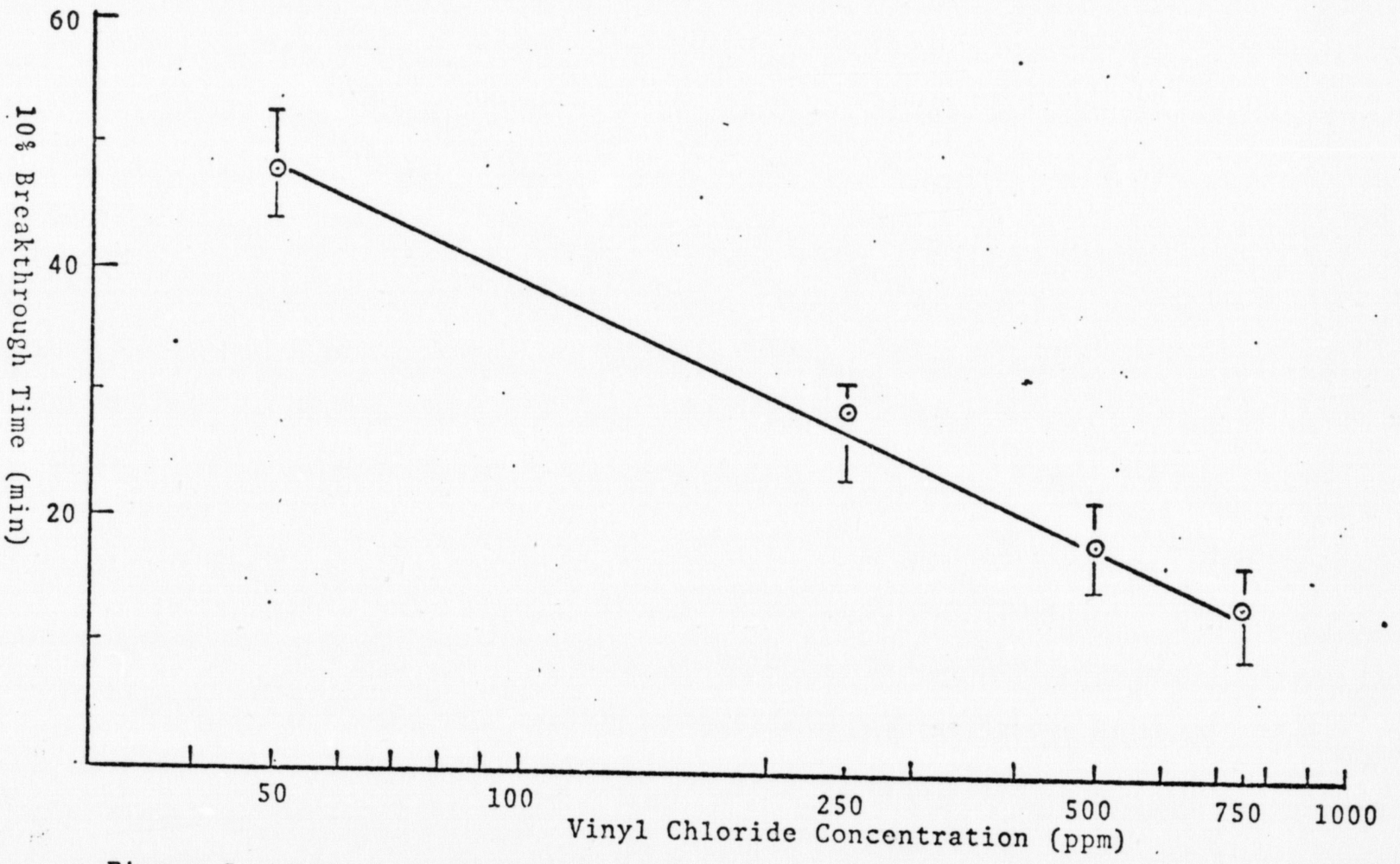



Figure 5. Effect of Concentration on Breakthrough Time
Cartridge Make #3

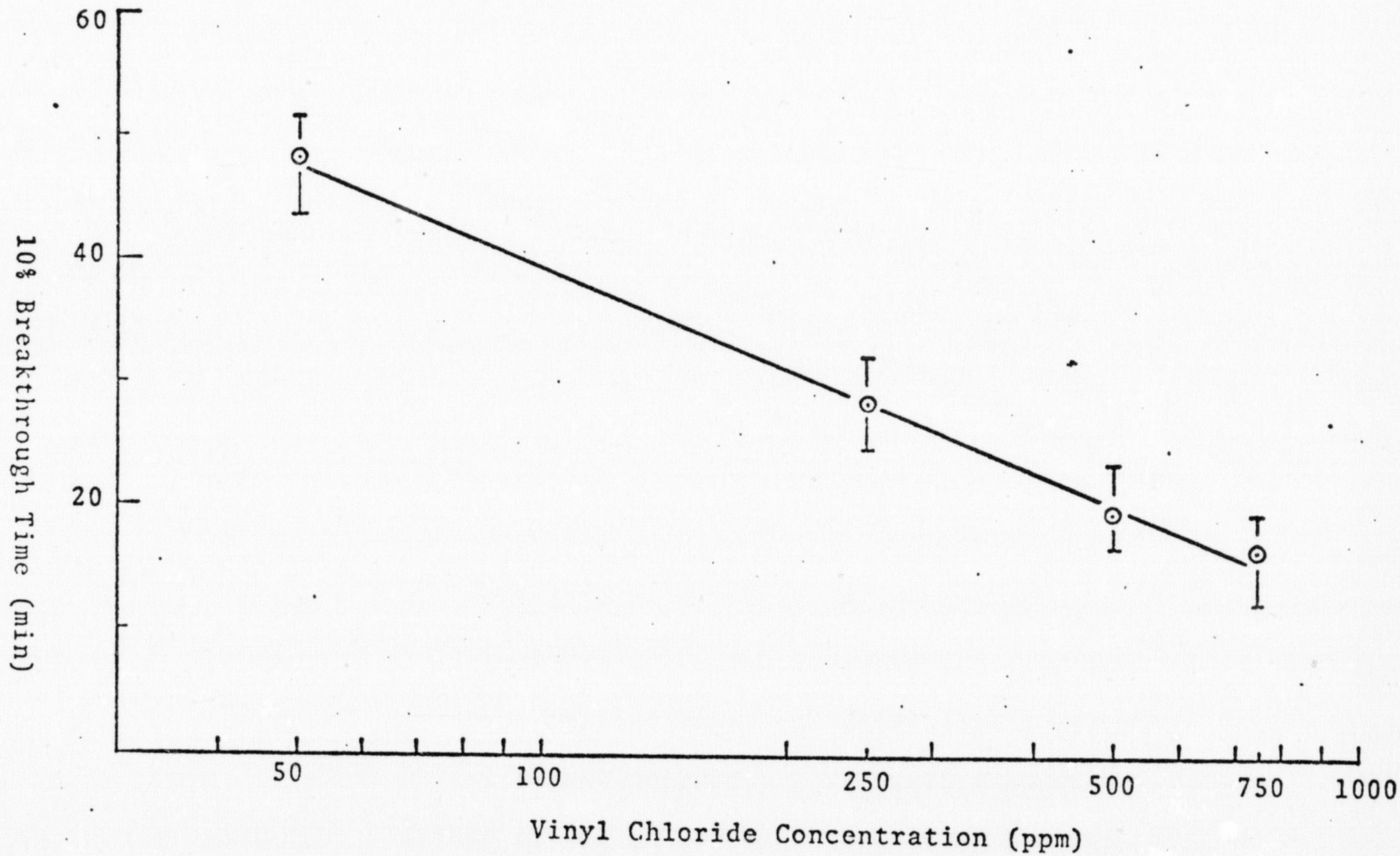



Figure 6. Effect of Concentration on Breakthrough Time
Cartridge Make #4

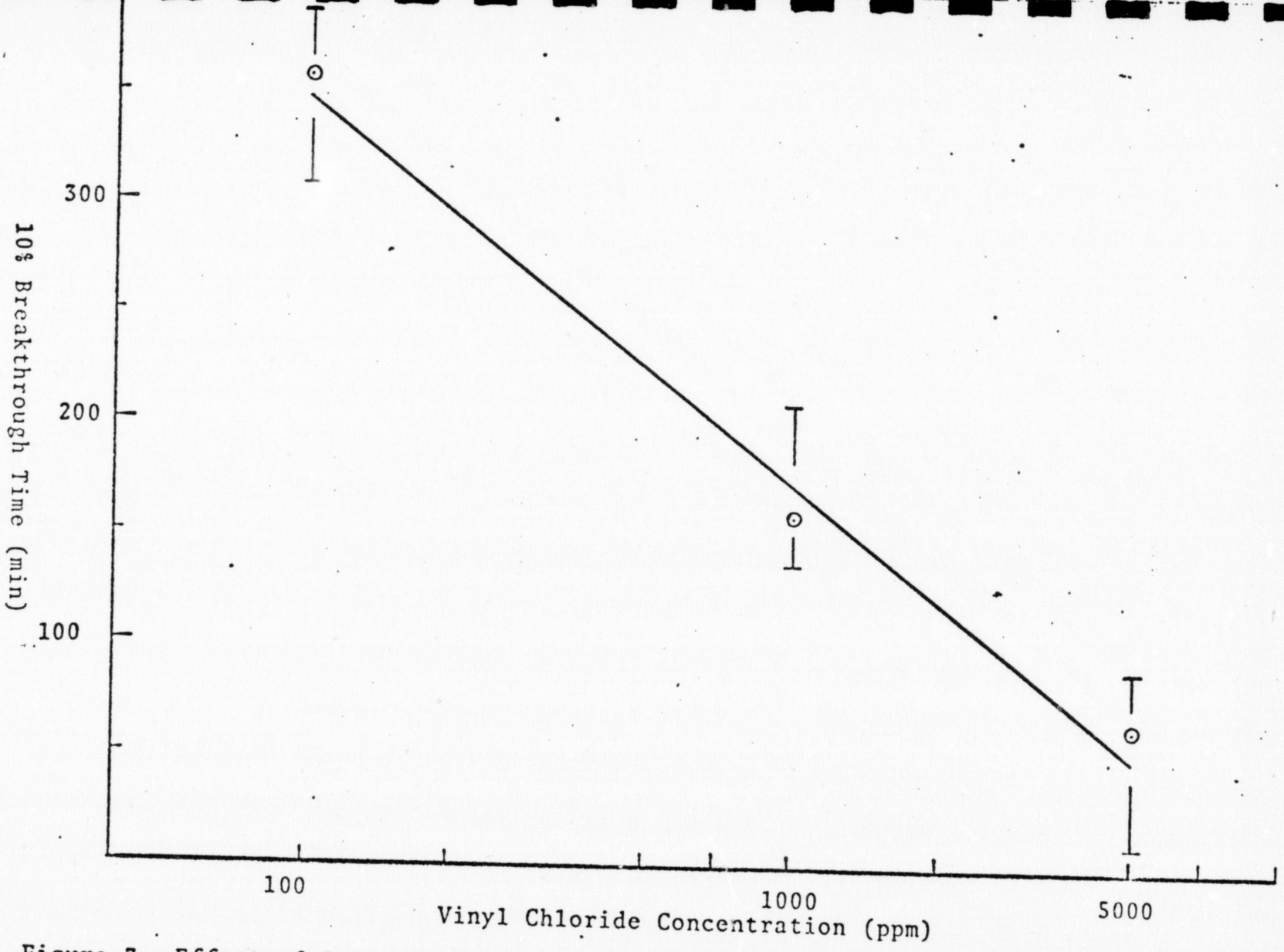



Figure 7. Effect of Concentration on Breakthrough Time - Canister Make #1

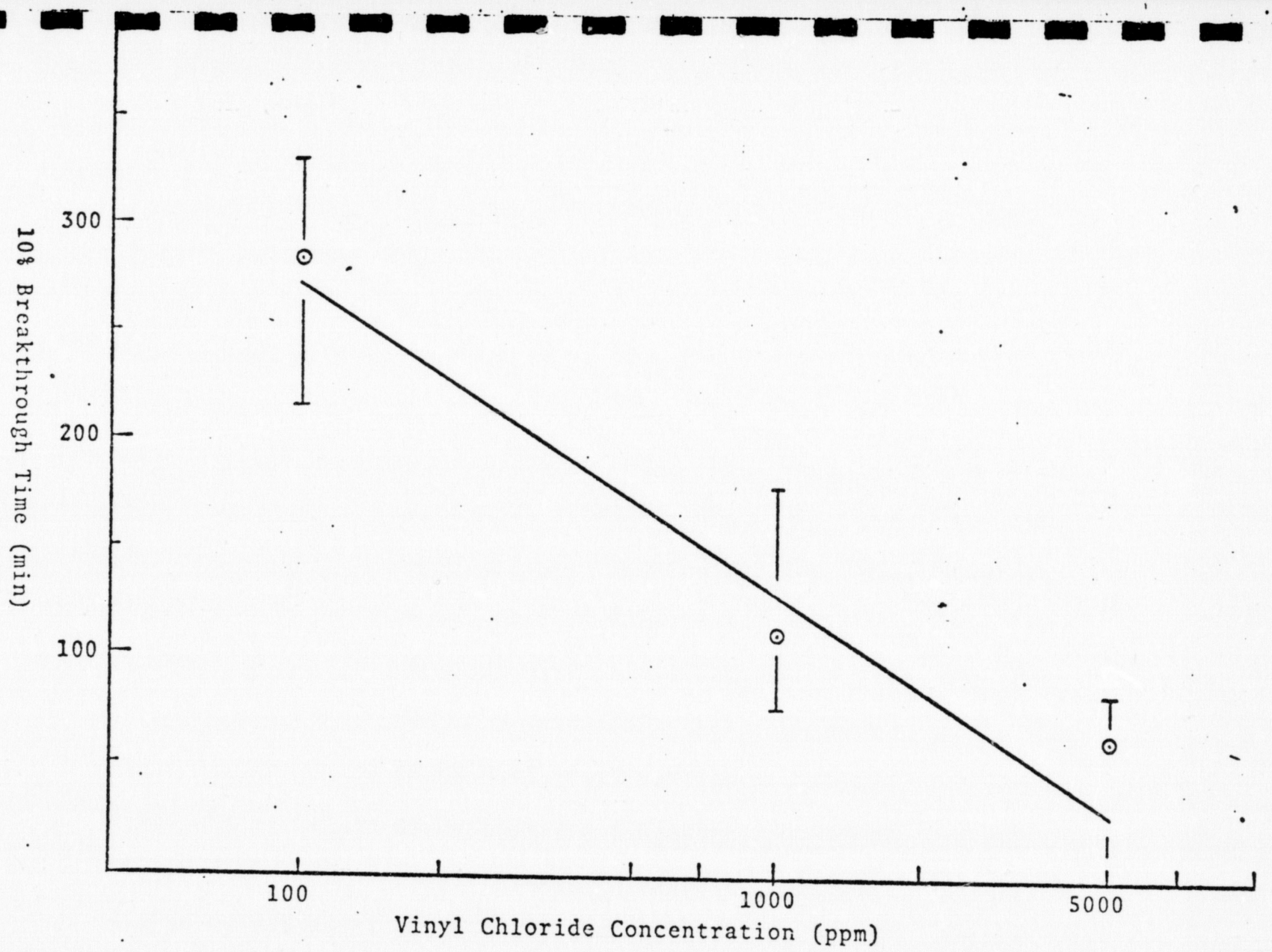



Figure 8. Effect of Concentration on Breakthrough Time - Canister Make #2

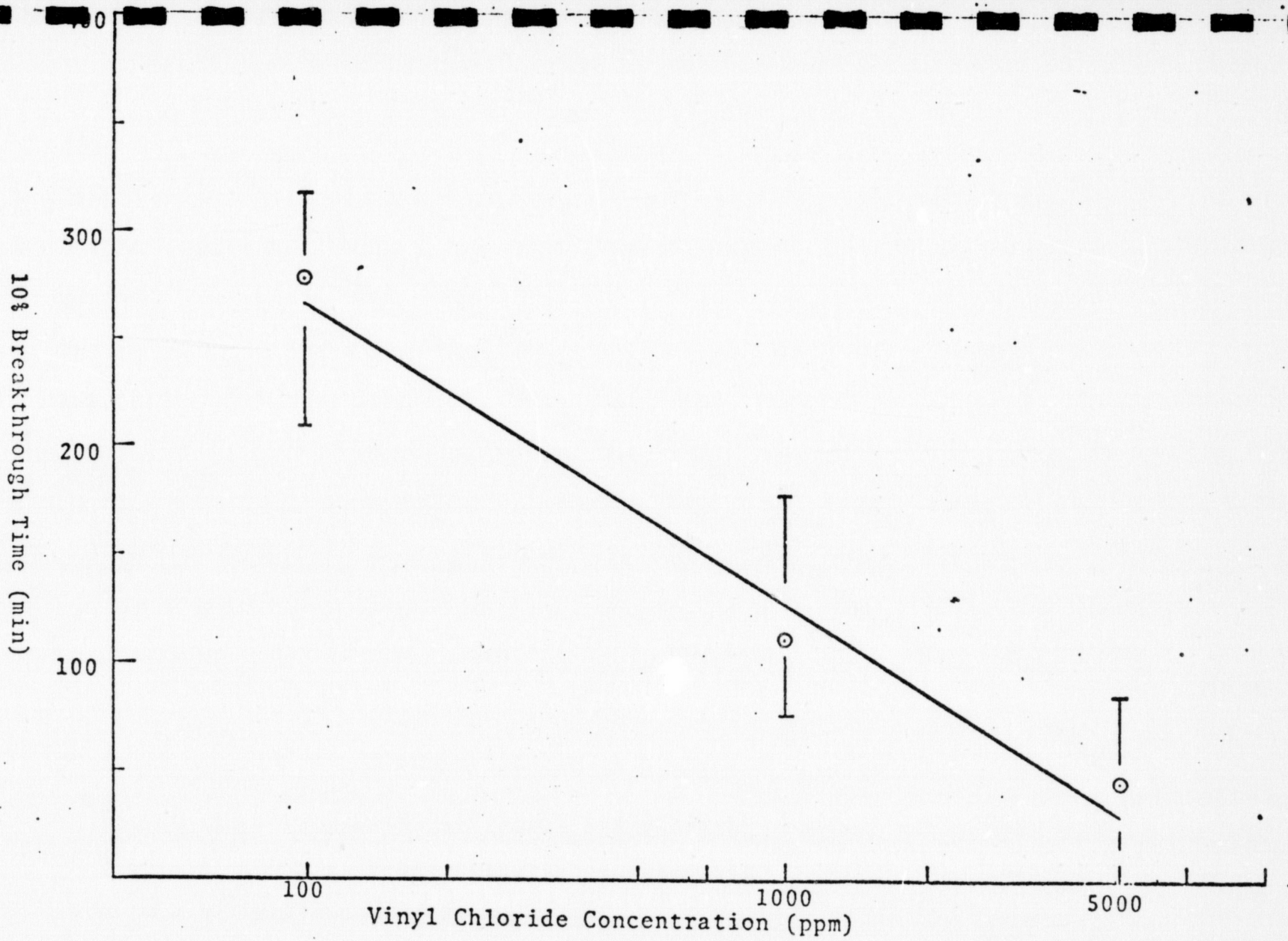



Figure 9. Effect of Concentration on Breakthrough Time - Canister Make #3

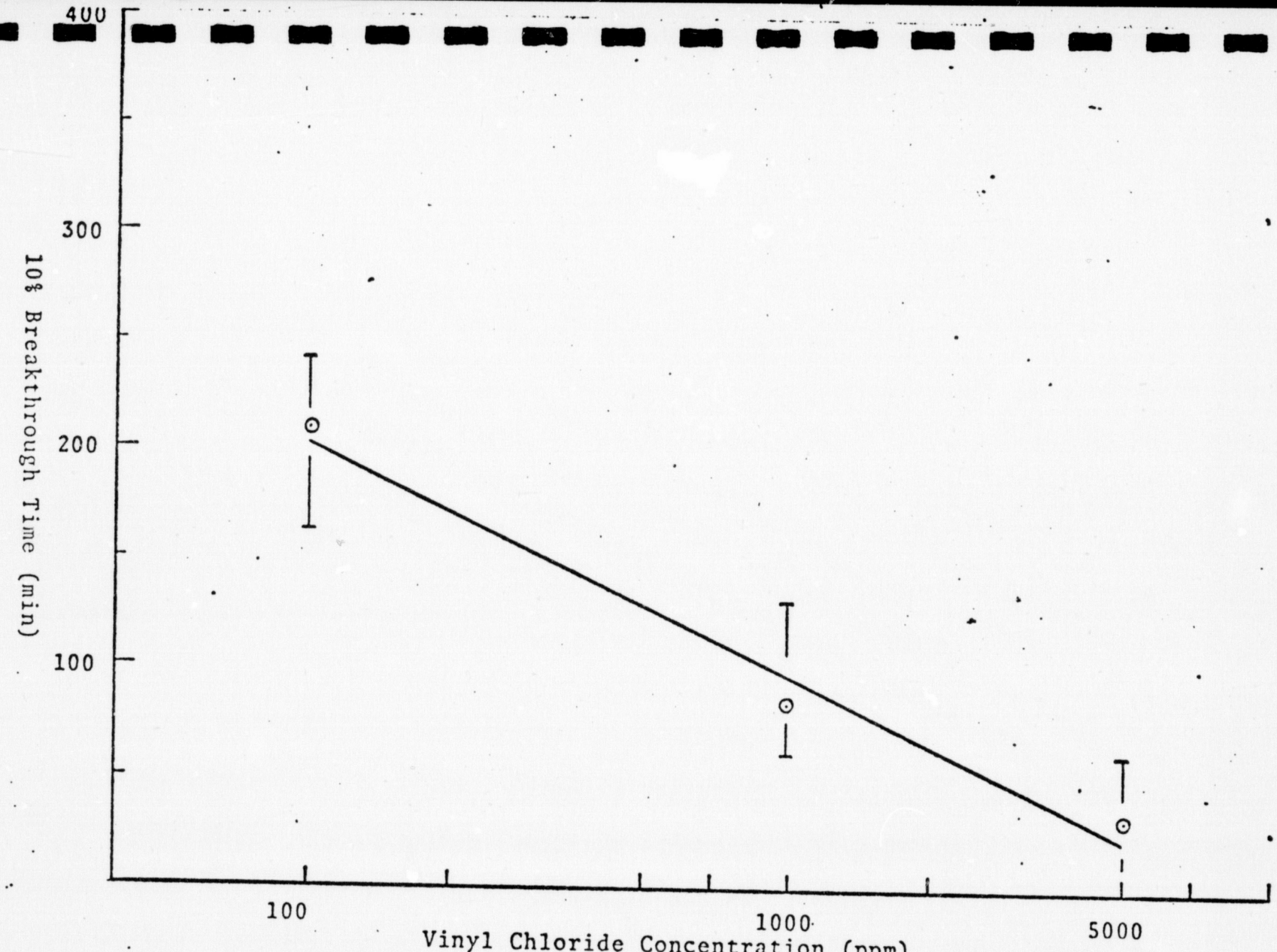



Figure 10. Effect of Concentration on Breakthrough Time - Canister Make #4

Table 5. Statistical Models of Breakthrough Data

Cartridges

| | Linear Equation* | Correlation Coefficient | 95% Tolerance Limits |
|---|---|---|---|
| Make #1 | $Y = 149.5 - 18.68\ X$ | 0.9814 | $Y \pm 8.63 \sqrt{1.09 + (.10)(X - 5.72}$ |
| Make #2 | $Y = 83.49 - 10.02\ X$ | 0.9929 | $Y \pm 2.85 \sqrt{1.09 + (.10)(X - 5.72}$ |
| Make #3 | $Y = 99.55 - 13.04\ X$ | 0.9938 | $Y \pm 3.53 \sqrt{1.09 + (.10)(X - 5.72}$ |
| Make #4 | $Y = 93.56 - 11.76\ X$ | 0.9931 | $Y \pm 3.30 \sqrt{1.09 + (.10)(X - 5.72}$ |

Canisters

| | Linear Equation* | Correlation Coefficient | 95% Tolerance Limits |
|---|---|---|---|
| Make #1 | $Y = 696.2 - 75.82\ X$ | 0.9935 | $Y \pm 33.3 \sqrt{1.14 + (.064)(X - 6.7}$ |
| Make #2 | $Y = 562.0 - 62.74\ X$ | 0.9862 | $Y \pm 47.6 \sqrt{1.14 + (.064)(X - 6.7}$ |
| Make #3 | $Y = 546.1 - 60.86\ X$ | 0.9853 | $Y \pm 47.7 \sqrt{1.14 + (.064)(X - 6.7}$ |
| Make #4 | $Y = 411.5 - 45.67\ X$ | 0.9877 | $Y \pm 32.7 \sqrt{1.14 + (.064)(X - 6.7}$ |

*Y = 10% Breakthrough time in minutes

X = $\log_e$ (Vinyl chloride concentration in ppm)

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# COMMENTS ON VINYL CHLORIDE

Frank G. Standaert, M.D.

September 20, 1974

Carcinogenicity, angiosarcoma: Vinyl chloride's capacity to induce angiosarcomas in animals is established. It has been shown in several laboratories, in several species (including fish, rats and mice) and at all concentrations tested so far.

Vinyl chloride's capacity to produce angiosarcoma in man has not been proven absolutely but the unusually high incidence of angiosarcoma among vinyl chloride workers and the similarity of the tumors in these workers to those produced in animals is as convincing evidence as it is possible to get without deliberate exposure of men. The few parts of the Record that question this conclusion point out that all of the cases have been concentrated in a few factories; seven of them occurred in the Louisville, Kentucky plant alone. This concentration raises the question of whether these workers received a greater exposure or whether other factors were operating in these individuals who succumbed. For instance, were there co-carcinogens present? Were there genetic predispositions to the disease in these individuals? Did regional dietary habits or environmental factors play a role? Was a latent or unknown infection or other disturbance a contributing factor? These are valid questions, but there is no way of knowing whether or not these possibilities influence the carcinogenic potential of vinyl chloride in man. Regardless, it should be

noted that these are only moderating factors. They do not detract from the conclusion that vinyl chloride can cause cancer in man.

Carcinogenicity, other tumors: Vinyl chloride produces several other tumors in animals. Indeed, angiosarcomas were only about one-third of the total tumors produced in the Maltoni and Biotest experiments. Malignant tumors of the kidney, lung and mammary glands each occurred about as often as angiosarcoma. In addition, tumors were found in virtually every other organ. As with angiosarcoma, these tumors have been observed in several laboratories, in several species, and at every concentration of the gas that has been tested so far.

The ability of vinyl chloride to induce tumors other than angiosarcoma in man has not been established. The Tabershaw-Cooper report (Exhibit 132) suggests an increased incidence of death from cancer among vinyl chloride workers but the increase is not statistically significant. On the other hand, detailed searches for other tumors have not been made and it is far more difficult, statistically, to prove the cause of common tumors than of those as rare as angiosarcoma. Hence the production of other tumors in man by vinyl chloride is still an open question. At this time it has been neither proven nor disproven.

Other hazards: The acute hazards of high concentrations of vinyl chloride, fire and anesthesia, have been known for many years. Non-lethal effects of chronic exposure to vinyl chloride also have been apparent for some time. Among the disorders produced are: acroosteolysis, Raynaud's phenomena, portal hypertension, fibrosis of the liver, broncoconstrictive disease, and

a variety of lesser lesions (Lange et al, Exhibit 183). The urgency of the angiosarcoma problem apparently has precluded careful study of other lesions in animals, but damage to brain, liver, kidneys, thyroid, bone, nerves and skin were noted by Viola some years ago and fibrotic changes in the liver are constant concomitants of the angiosarcoma. The Biotest data clearly show early and excess deaths among animals exposed to all concentrations of vinyl chloride tested. Studies of teratogenic effects in animals have not had positive results but hints of possible mutagenic effects in man can be found in the excess chromosome splitting seen in Selikoff's laboratory. The possibility of teratogenicity is raised by Maltoni's observation of angiosarcomas in newborn animals.

Conclusion: The attention that has been given to angiosarcoma of the liver should not encourage a narrow view of the hazard of vinyl chloride. Even the limited data that is available on human toxicity clearly shows the gas to cause changes in virtually every organ in the body. The animal data shows that angiosarcomas are less than one-third of the total number of tumors that can be produced and that other damage is commonplace. In short, the record is replete with evidence that vinyl chloride is a serious potential hazard to the health of man.

Polyvinyl chloride: The Record only touches on the toxicity of polyvinyl chloride, but there are suggestions that it may not be inert. At the least, it is a carrier of the entrapped monomer. In addition the particles are phagocytosed and enter many organs. There are suggestions that they may cause pneumoconiosis

Quantitative aspects of the hazard: The record contains very little data on how much exposure to vinyl chloride it takes to injure workers. With regard to animals, it is clear that 50 ppm, four or seven hours a day, five days a week for a lifetime is a powerful carcinogen but there have been no experiments at lower concentrations and therefore there is no way of knowing whether lower concentrations are also dangerous. I have been told that experiments with lower concentrations have begun but it will be at least a year before significant data are available.

The Record contains no reliable information with regard to the quantity of vinyl chloride that is hazardous to man. Manufacturers did not monitor the concentration of the gas until recently and we don't know what conditions prevailed in their factories. We don't know how much vinyl chloride workers have been exposed to and therefore don't know how much was tolerated safely or how much it took to cause injury. Several exhibits contain estimates, but these are based on memory, odor, and impressions of observers. Attempts have been made to translate these to actual gas concentrations but the results are nothing more than "educated" guesses.

There is comfort in the fact that there are no cases of angiosarcoma in factories where management was concerned about the potential for toxicity and therefore presumably took more precautions, but the two cases in individuals exposed to low concentrations in Connecticut are extremely disturbing. The only source of comfort in them is in the report that their lesions are not exactly the same as the angiosarcomas in other individuals or in laboratory animals (Exhibit 164) i.e., these may not be vinyl chloride related lesions.

It is even more difficult, if that is possible, to ascertain the amount of vinyl chloride that produces noncancerous lesions. There is virtually no quantitative information for either animal or man and there has been no attempt to quantitate the occurrence of these lesions, or the concentrations of vinyl chloride that cause them. This is a major gap in our knowledge. More workers may suffer from these effects than from the carcinogenic effect.

There is no clue to the villain in the toxicity produced by vinyl chloride. It could be the intact molecule or it could be a metabolite or a reactive intermediate. Several metabolites have been found and several potential routes of metabolism have been illustrated, but which of these, if any, leads to carcinoma and other changes is not known. There is also evidence that the metabolism of vinyl chloride is concentration dependent with one pathway predominating at higher concentrations and another at lower ones. These data obviously would be significant if it were known which route led to the deleterious material, but the critical insight is not available.

The Record contains many discussions of the dose-response relationship between vinyl chloride and its toxicity, but the data needed to establish the critical part of the relationship are absent. Every concentration tested so far has produced tumors and excessive rates of death in animals. Some scientists have taken numbers from these experiments, and have attempted to project the dose response curve below the observed values. Such projection is speculative, at best. Even at the high end of the curve, the data are scanty and give a poor basis for line fitting. They give no grounds for extrapolating to the unknown. More fundamentally,

there is no proven or theoretical reason for extrapolating the curve. We do not know whether there is an absolute threshold for the toxic effects of vinyl chloride or whether the toxicity grades continuously at ever lower doses. Our knowledge of other carcinogens could support either hypothesis and there is no reason to choose one over the other with respect to vinyl chloride. In short, the only factual statement is that 50 ppm is toxic for animals and nothing is known about the effects of less than 50 ppm.

Finally, there is no way of projecting from the animal data to man. The Record shows the mouse to be the most sensitive of the mammalian species tested in the laboratory. The Record also shows that hamsters are substantially more resistant and that there are differences between Wistar and Sprague-Dawley rats. Thus, there is documentation of species and strain differences. Arguments have been made that man has a substantially lower rate of respiration and metabolism and therefore he should be less susceptible than a mouse to the carcinogenic effect. It has also been argued that man's exposure is less intense in that it normally begins in adult life and is not continuous, i.e. workers take vacations, holidays, sick-time, they change jobs and there are variations in factory conditions. There is also a suggestion in the record that factories with generally lower concentrations of vinyl chloride have had no cases of angiosarcoma.

The Record contains many allusions to these facts and innumerable remarks to the effect that a man is not a mouse and that his susceptibility should not be equated with that of a mouse. The implication is that OSHA's standard should not be further reduced without direct evidence on the susceptibility of man. This kind of logic points to a path which is dangerous

to follow. As noted above, it is as clear as it is possible for it to be that a similar set of toxic effects occurs in man and experimental animals. It is also clear that among the experimental animals there is no great difference in the concentrations of the gas that produce effects in the various susceptible species. Under these circumstances, there is only one prudent course to follow: assume that man is at least as sensitive as the most sensitive mammalian species. This assumption is universally applied in assessing the toxic hazard of materials to man. The potential for disaster in any other course is apparent.

Time factors: There is a similar void in our knowledge of the time it takes to produce carcinomas. In animals the tumors do not appear soon after exposure. Instead, there seems to be an inverse relationship between concentration of gas and time to onset of tumors, and in some cases the time to onset approaches the lifespan of the animal. Much has been made in the Record of these facts and the fact that the human victims worked in the vinyl chloride industry for many years before their tumors were diagnosed. However, we have no way of translating these observations into practical guidance. We do not know if this long time to onset is an induction period; that is, a long, continuous exposure to the gas is necessary to produce the fatal change; or whether it is a latency period; that is, the tumor begins its inexorable course very soon after exposure but its initial growth is slow and its recognition is delayed.

The Record hints that the former may be the case. There is a suggestion in the recent Maltoni data that long continuous exposure is

needed to produce tumors, but the data are few and preliminary. Some theoretical considerations are in the same vein. Broken strands of DNA are known to be reparable and it is thought that immune processes car kill abnormal cells early in the carcinogenic process. Similarly, Dr. Popper's theory that the angiosarcoma is a result of a precursor fibrosis suggests a critical length of exposure. These observations are enticing, but are not adequate to form a conclusion. There is no way of knowing whether the theories are applicable or if they are, of estimating the time at which the process changes from reversible to irreversible.

In another regard, it is important to realize that the apparent lag time for some of these hazards, particularly carcinogenesis, is so great that improvement in working conditions may not improve morbidity for a decade or more. That is, we can expect to see the consequences of the higher exposures that have existed up until now. In addition to the human tragedy associated with this continuing morbidity and mortality, there is the possibility of misinterpreting the data. Some may not recognize the time lag and may take the failure to reduce morbidity as a sign of failure to set the standard low enough.

As the ultimate irony, the apparent lag time in the production of human disease among those exposed to vinyl chloride is such that the Assistant Secretary will probably never know whether or not he made a correct decision.

Conclusion: Vinyl chloride has to be presumed to be hazardous to man, causing a series of acute, chronic and fatal diseases. All of these

effects have been produced by concentrations that existed in the work place in the past, but virtually nothing is known about the circumstances that produced them. The deficit in our knowledge is so great that there is no hope of getting adequate quantitative data in the foreseeable future and a full explanation of the hazard is probably several decades away. Since we do not and cannot know what concentration of vinyl chloride is dangerous for man, it will not be possible to set a standard on a solid basis of fact. The best that can be done is to try as hard as possible to reduce the potential medical risk without incurring unacceptable economic risk.

Recommended approach--Philosophy and tactics: An important factor is the special terror of cancer in our society. The risk of violent death or injury is accepted by workmen in many industries. The risk of chronic disease has also been accepted in certain industries, (e.g. "black lung"). Cancer is not and will not be viewed as sanguinely by the American public and workman.

The tactics for achieving a reduction in exposure are not in my area of competence, but the following observations may be helpful. To me, it does not seem likely that vinyl chloride can be banned without damage to our economy. It also does not seem likely that human exposure can be eliminated immediately. Therefore, some risk will have to be borne by some individuals. In my view, this risk should be as small as possible and it should be confined to the smallest possible number of people. Those at risk should be fully aware of the risk, accept it voluntarily, have the best means of protecting themselves against it, and be compensated for bearing

it. There should be no risk to the innocent, the ignorant or the unsuspecting.

Since there are several different populations exposed to vinyl chloride, I suggest the following:

1. Reduce the residual vinyl chloride in the polymerized product. The greatest number of people presently exposed to vinyl chloride are those using the polymer. The concentration in their environment is small, but it is not known whether or not this concentration is safe and, accordingly, it should be reduced or, if possible, eliminated. Furthermore, most of the people working in these factories are ignorant of the risk and unsuspecting of the hazard. Almost all of the exposed females are among this group of employees. The companies these people work for are the least capable technically and financially of monitoring and controlling gaseous vinyl chloride. All of these problems can be solved by preventing vinyl chloride from leaving the polymerizing plants. Therefore, I suggest that every effort be made to encourage manufacturers to strip the monomer from their products.

In addition to eliminating or reducing the exposure in the fabricating plants, this approach would have the extra benefit of protecting those who transport polyvinyl chloride. Some of the highest gas concentrations reported in the Record were found in trucks and freight cars that had been filled with polymer, sealed, and shipped through the heat. Workers should be protected against the possibility of exposure if they should enter such a vehicle.

Finally, insisting on clean polymer would reduce the threat of unfair competition from foreign manufacturers whose occupational standards

may be less stringent and, therefore, less costly than those imposed on American companies.

In this regard, the record suggests that little thought has been given to the technology for stripping the monomer. Therefore, this may be an area in which very large gains might be made with relative ease.

2. I suggest a reduction in the emphasis on ventilation as a means of reducing exposure in the monomer and poly plants. lators perforce distribute the gas to the surrounding environment a: cord is filled with observations of significant concentrations in offices, laboratories, open areas and even beyond the fence line. Some of these concentrations are uncomfortably high. The public and unsuspecting workers should not be exposed in this way.

3. Following the theme that the area of risk should be as small as possible, I suggest different standards for different groups of people. I suspect that the general public and workers at end-product plants can be protected much more quickly and easily than those engaged in polymer production. I see no reason why a low concentration standard for these people has to be delayed until more difficult situations in the polymerizing plants can be solved.

I recognize that setting different standards for different groups may be taken by some as callousness, i.e. a different concern for one group of workers than for another. This isn't the case. The purpose of separate standards is to reduce the exposure for everyone at the rate that is possible in each area. Permitting exposure of some workers to high concentrations

may be unpalatable, but the converse is even more unpalatable to me, i.e. that all workers shall be permitted to be exposed to high concentrations. Similar "double standards" are commonplace in our society. An obvious example is found by comparing the TLV's for workers to EPA's standards for the populace.

When considering separate standards, it is most important to remember that there is no known risk in American factories. All injuries that have been documented are presumed to have been caused by conditions that are different from present ones. At the hearing, many stated their opinion that the Temporary Standard provides conditions that are perfectly safe. Thus, a lower standard is being considered, not because the present one is known to be inadequate, but because it might be. In this context, different standards for different segments would not require anyone to work in a place known to be dangerous. They would instead, be a prudent way of operating in a potentially risky situation, much like evacuating non-essential personnel from a potential danger area while permitting essential personnel to remain.

Approach to a standard: Clearly a standard cannot be set on the basis of factual medical, toxicologic, epidemiologic, or pharmacologic data. Such data do not exist. All that can be proven is that 50 ppm inhaled for several hours a day for many months is extremely toxic to rodents. Traditional toxicologic reasoning would prohibit comparable exposure of human beings. Therefore, the upper limit of any standard should be well below 50 ppm TWA.

Unless vinyl chloride is banned outright, the lower limit of a standard will be dictated by analytic technology. The practical lower

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limit is one that can be observed, monitored, and enforced. This means it must be within the capability of current analytic technology. The hearings were not specifically directed at this, but the concensus seems to be that the NIOSH recommendation is probably a good appraisal of the equipment that is available for routine field use today and that this equipment is capable of one ppm. Therefore, one ppm becomes the lowest reliably detectable and enforceable limit.

The term "no detectable amount" deserves comment. It has substantial appeal, but it is fraught with potential mischief because what is or is not detectable will vary from circumstance to circumstance and from time to time. The mere existence of such a term is a challenge to the analytic chemist to sharpen his tools and push the frontier downward, and the state of the art of organic analysis is such that major advances can be made in a short time. Thus a "no detectable amount" standard becomes infinitely elastic and subject to constant redefinition. The manufacturer who in good faith purchases and installs the best equipment available today may find himself challenged tomorrow by someone with a new technology. Even worse, the present wording is extremely ambiguous. Almost everyone at the hearing interpreted it to mean a standard of 1 ppm, but that is not what the document says. It says "no detectable amount, as determined by a . . . method capable of detecting . . . 1 ppm". Thus, this standard really doesn't specify a vinyl chloride concentration; it specifies the <u>minimum</u> sensitivity of the analytic equipment. This seems to me to be an illogical way to set a standard.

If the standard is to be this low, a better approach would be to state it in accord with reality. That is, determine the lowest concentration that can be detected by equipment that is: available now, available from several manufacturers, adaptable to the purposes to which it will be put, reliable under field conditions, and can be operated by technicians of ordinary competence and use this level as the standard until such time as instruments with the same qualities but greater sensitivity are produced.

Medical Surveillance: Regular examinations would be of questionable value if their only purpose were to detect angiosarcoma. Reasonable people can easily disagree on the virtue of early detection of an untreatable and fatal disease. However, there are other reasons for desiring medical examinations of workers who are regularly exposed to vinyl chloride. One is epidemiologic; we need to know more about the human experience in this industry. The more compelling reason stems from the evidence that vinyl chloride may cause a variety of disorders, some of which (e.g. bronchoconstrictive disease, vascular hyperactivity, fibrosis of the liver) might be reversed or, at least, arrested if detected early.

For these same reasons, the medical examination should not be aimed exclusively at tumors of the liver, as that in the Proposed Standard seems to be. It should be broad and complete. Specific recommendations follow, but it should be clearly understood that these are suggestions for minimum examinations. The regulations should be written so that there is no way of missing the intent and interpreting the stipulated tests as the only things a physician should do. Attention should be

given to the major potential target organs, but it should not be limited to them.

History-complete; including previous illnesses, previous employment, exposures to toxic materials, alcohol intake and dietary habits.

Physical-complete; including skin; limbs; vascular system; lungs; heart; abdominal organs.

Laboratory; chest x-ray; complete blood count including smear for differential and estimation of platelets; urinalysis including microscopic examination; chemical analysis of blood, including SMA-12; liver function and serum enzyme determinations; hepatitis associated (Australian) antigen, and (where available) carcinoembryonic antigen and alpha fetoprotein; pulmonary function tests ($FEV_1$ and FVC).

The medical examination should be done by a licensed physician, preferably one experienced in industrial hygiene, and the laboratory work by an accredited and licensed laboratory. (Physicians familiar with the toxic potential of vinyl chloride should be available to all of the monomer and polymer manufacturers. They are not as likely to be available to the many processers of the polymer--another reason for trying to contain the monomer within the confines of the major plants.)

Annual examinations should be adequate. Abnormal findings should be checked as quickly as possible and appropriate additional examinations should be done to find the cause of abnormalities.

Records should be maintained at least for the lifetime of the employee, preferably for several years longer; it would be very helpful

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to establish a central repository if appropriate means of doing so can be found.

Since there is no knowledge of the course of the toxic effects produced by vinyl chloride, there is no way of knowing whether or not an employee who developes abnormalities should be removed from contact with the material. On the one hand, the processes may be reversible and removal from contact would be beneficial; on the other hand, the processes might not be reversible and removing one worker and filling the job with someone else may only multiply the number at risk. There will be no means of resolving this dilemma until we know more about the course of vinyl chloride toxicity. For now it would probably be best to assume that early stages are reve ible and act accordingly.

Miscellaneous: Other parts of the proposed standard also call for comment. The requirement for impermeable clothing seems to me to be excessive. There are few studies of the penetration of skin by vinyl chloride but those few that are available (see Dow Report) suggest that while vinyl chloride can enter by this route, it does so in very small amounts and at a very low rate. This is in keeping with theory which would predict that a gas of moderate lipid solubility (such as vinyl chloride) would be able to penetrate the skin but at a rate vastly slower than through the lungs. On the other hand, a gas with solubility in water as low as that of vinyl chloride would be expected to be exhaled almost as soon as it entered the blood stream. Thus, a man respiring clean air should retain virtually none of whatever little gas enters through his

skin. Therefore, I do not see any need for impervious suiting under anything except the most extreme conditions (prolonged exposure to many thousands of parts per million of vinyl chloride). The use of ordinary protective clothing to reduce the exposure to polymer and entrapped liquid vinyl chloride would be desirable.

The Record suggests that there is a fortuitous relationship between polymer and air such that a polymer containing, for example, 50 ppm of monomer can produce an air concentration that is also 50 ppm. This relationship should not be allowed to confuse the reader. A careful distinction should be made between gas concentration in air and monomer concentration in polymer. Both may be expressed in the same units, but their importance is entirely different. For example, an upper limit of 1 ppm of gas in air may be a necessary and attainable goal for major segments of the industry, but 1 ppm of monomer in polymer is probably neither necessary nor attainable. Therefore, if a purity standard for polymer is set, it should be different from that set for air. The Record suggests that plants handling polymer with 50-100 ppm of monomer are having little or no difficulty maintaining less than 1 ppm in the working area.

The Record suggests to me that area monitoring is feasible and desirable. It also suggests that personal monitoring should also be done, particularly for those whose jobs cause them to move from one area to another.

I am not competent to choose among the various types of respiratory protection equipment, but to me it seems that a strong case has been made

for permitting cannister-type equipment for emergencies and for short term use by those whose jobs require mobility.

With regard to air supplied equipment, it should go without saying that the air should not be contaminated, but given present factory environments some precautionary words may be in order.

There should be careful distinction among contact with liquid monomer, gaseous monomer and polymer contaminated with monomer. The Proposed Standard seems to equate them, but each has a different problem and a vastly different hazard. The final regulations should distinguish among them and prescribe protective clothing, hygenic practices, and medical treatment and surveillance that is appropriate to the hazard.

In this regard, it should be remembered that vinyl chloride is a gas which will not cling to skin or clothing and, therefore, is different from solid or liquid industrial hazards which stay until washed off. It should also be remembered that the toxic effects of the gas are extremely delayed in onset. They will not be detected or prevented by prompt medical examination.

The requirement for an immediate shower after exposure also is unnecessary. Washing the exposed part and being prepared to deal with freezing injury are worthwhile, but the volatility of vinyl chloride is such that none would be expected to remain on the skin for a significant time after exposure. On the other hand, anyone exposed to liquid vinyl chloride to the extent that there is skin damage should receive

immediate medical attention. The "within twenty-four hours" requirement is not adequate.

I am sympathetic with those who object to the proposed signs and labels in that they are frightening without telling the individual what it is he should be frightened of, or how to avoid danger. The label should contain the name of the material, recognize that cancer is not the only (or even the most likely) form of health hazard, and give instructions or precautions for avoiding the hazard.

A final expression of a personal prejudice: "Level" is laboratory jargon. It would be nice if the final document could refer to concentrations instead of levels.

V-202

DAVID H. WEGMAN, M.D.
18 PERKINS STREET
ARLINGTON, MASS. 02174

September 20, 1974

Donald Boyd
Office of Standard Development
Room 610
1726 M Street, N.W.
Washington, D.C.

Dear Mr. Boyd:

Enclosed is my report on the medical and biologic hazards of exposure to vinyl chloride. It is based on all the material which was sent me and which I frankly found overwhelming. At your suggestion I have made the report brief and in summary form. It would seem that this is the organization of the large volume of material which will prove most useful to you at this point in the development of the vinyl chloride standard. I hope this assumption is correct, for a complete epidemiologic and medical evaluation of the information regarding vinyl chloride would be long, detailed, technical and would most likely bury the essential conclusions.

As I read through the testimony and accompanying documents (some of which arrived only the beginning of this week), I was dismayed at the amount of repetitious material and information of little use. There was, in sum, only limited information available which was original, based on sound principles of medicine and epidemiology and useful for my report.

You will remember I attempted to elaborate on some of my findings during the meeting with Mr. Stender. His question regarding the scientific certainty for the identification of a specific number was distressing. I am afraid that there is no data upon which to suggest, with certainty, a specific number which I or anyone else can assure you will be a safe exposure level. I urge you to plan reconsideration of this standard in three years when studies which have only now begun will have provided us with a better foundation. I fear, however, that an accurate answer to Mr. Stender's question will never be known.

As I understand it you did not wish me to suggest specific language for the standard and I have not. I have, however, added brief comments on non-medical sections of the proposed standard which appeared pertinent.

I do not envy you the task before you. Please let me know if any further information would prove useful. If elaboration of any section of my comments is desired I can be reached by phone at 617-727-3982.

I was not provided any specific instructions regarding submission of expenses. I have enclosed a cost account for my trip to Washington and my airplane ticket receipt. Will you let me know how payment for expenses and services will be made?

Sincerely yours,

David H Wynn, MD

# RECOMMENDATIONS FOR A VINYL CHLORIDE STANDARD BASED ON BIOLOGIC AND MEDICAL DATA

A review of the data made available through the Hearings and other published material leads to the recommendation of an exposure to vinyl chloride of no greater than 1 ppm. This conclusion is based on the following facts.

1. A review of the animal studies of which we have preliminary results makes it clear that at least two species are subject to tumors following long term exposures to vinyl chloride. It is generally accepted that these animals develop tumors at levels as low as 50 ppm. The dose-response relationships are still being explored as experiments at lower exposures have been initiated. In addition multiple tumor sites have been observed in exposed animals. It would appear, that not much more is to be expected from this resource as the animal lifetime is short and the numbers necessary for significant tests are becoming large. In summary, the animal data support three major conclusions: a) multiple species are susceptible, b) multiple organs are at risk of cancer in the animals and c) levels as low as 50 ppm are not safe.

Extrapolation to man from animal studies is extremely difficult but we must consider man at least as susceptible to vinyl chloride as the animal species. Although not often used, extrapolation by way of a safety conversion factor is possible.

From these data alone a level of 0.5 ppm is suggested.

2. Four studies of mortality have been reported which have reasonable designs and are sufficiently free of design bias to warrant further review. Unfortunately several reported studies looked only for angiosarcoma rather than seeking all disease which might be in excess. Others were too heavily biased by large numbers of recent employees to allow any conclusions to be reliably drawn.

a. Dr. Wagoner of NIOSH has completed 70% of a study of persons who died having worked at Pottstown or Louisville. This group was selected for 5 years of exposure and at least ten years since onset. Already excessive liver, brain, lung and blood tumors are evident.

b. Dr. Nicholson's study of the Niagra Falls plant is defined in the same fashion. Liver cancer is excessive and there is a suggestion of brain and blood tumors being excessive.

c. Dr. Monson's study of Louisville workers shows two imimportant results. The multiple organ involvement is again noted with liver, biliary tract, lung and brain cancer. A disturbing additional finding is that a trend is revelaed which shows an increase in proportion of cancer over time.

siderably more frequently than expected. In addition, Swedish laboratory tests have shown mutagenesis in an animal test system.

In summary the animal studies make clear that any human exposure level must be less than 50 ppm. How much less than this appears indicated by the human studies on malignancy, non-malignant disease and mutagenesis. There is no single material currently in use which has been shown to affect as many different parts of the body with such devastating impact as vinyl chloride. Were it possible to eliminate it from the market, this would be by far the wisest choice. If it must be used, human exposure must be kept to the absolute minimum. Exposure to more than 1 ppm is not medically defensible.

## COMMENTS ON OTHER PORTIONS OF THE STANDARD

1. The variance system, not a staged standard, should be used to allow introduction of technological controls.

2. A list of required medical screening tests and procedure needs to be included or most physicians will be left not knowing what is sufficient.

d. Dr. Tabershaw's study is of a large part of the industry. This study suffers from too many recent employees who have not been employed long enough to be affected. The analysis underepresents those who died as follow-up was not complete. Even so, the results suggest increased lung, brain, blood and digestive system cancer.

In summary, the human mortality data demonstrate a rising number of deaths due to cancer and many different types of cancer associated with work exposure to vinyl chloride.

3. Non-malignant disease. Studies by Dr. Lange in Germany suggest that exposures to vinyl chloride experienced in the manufacturers who use only the finished resin (approximately 5-10 ppm on average) are associated with multiple organ disease. They have preliminary evidence of a chronic liver disease, splenomegaly and thrombocytopenia. Dr. Selikoff's studies in Niagra Falls are showing evidence of liver disease, splenomegaly, pulmonary ventilation defects and peripheral vascular disease. There is no accurate measure of dose associated with these acute and chronic changes.

4. Mutagenic effects. There is preliminary evidence in a study of chromosomes of 11 vinyl chloride workers compared with ten controls that chromosome changes are present con-

3. Medical records and monitoring results must be maintained not only for the lifetime of an exposed individual but should be maintained afterwards. Were such information available now, well after the deaths of past vinyl chloride workers, we would be much better informed about this problem.

4. A full face canister respirator should be permitted for specified uses for limited time periods. Shortcomings of current respirators could be alleviated if manufacturers have an incentive.

5. Signs and labels. Vinyl Chloride is not a cancer-suspect agent, it is a recognized carcinogen and should be labeled as such.

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# MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

TO : Alexander J. Reis
Assistant Secretary

DATE: September 24, 1974

FROM : Director, Division of Field Studies and Clinical [illegible]

SUBJECT: Evaluation of the Tabershaw Cooper Associates (TCA) Epidemiologic Study of Vinyl Chloride Workers

As you requested in your memorandum of May 22, 1974, my staff and I have critically reviewed the TCA epidemiologic study of vinyl chloride workers.

Attached for your perusal is that review.

Joseph K. Wagoner

Joseph K. Wagoner, S.D. Hyg.

Att.

# EVALUATION OF THE TABERSHAW COOPER ASSOCIATES (TCA) EPIDEMIOLOGIC STUDY OF VINYL CHLORIDE WORKERS

The TCA epidemiologic study makes use of the [illegible] cohort technique which is one of the more powerful epidemiologic approaches for studying chronic diseases such as cancer. However, the results generated from this type of study can be misleading when proper attention is not given to 1) the integrity of the basic data collected, and 2) the impact of pertinent parameters of risk. Such is the case for the TCA study, specifically with regard to latency, exposure, and vital status ascertainment.

Latency as applied to the TCA study is the time from initial exposure until death or the study cutoff date, December 31, 1972. Latency differs from exposure duration only when a person does not work continuously in an exposed job until his death. It is well known that environmental carcinogens usually do not manifest their effects in man until fifteen, or more commonly, twenty or more years after initial exposure. As an example, of all the angiosarcomas presently identified in vinyl chloride polymerization workers, all were in persons with eleven or more years latency, and 80% were in persons with fifteen or more years latency. Thus, persons exposed to a carcinogen less than, say ten years ago, would not biologically be expected to manifest a cancer of industrial origin and therefore would obscure the true excess cancer risk among those individuals having achieved ten (10) or more years by disproportionately elevating the "expected" number of cancer

deaths in the combined cohort. The TCA study contains this "latency bias" by including persons who had as little as one year latency, i.e., started December 31, 1971 and worked until the study cutoff date.

In addition, one plant in the study included only records of persons working or terminating during the last six (6) years even though this is the oldest plant in the United States, having started in 1938. As a result many of those persons with the longest latency were not included since they quit prior to five years ago, while almost everyone who started between one and five years ago was included. This selection criteria tends to bias the sample towards those persons with shorter latency, and away from those persons in whom environmental carcinogenic manifestations would be found. When the authors mention, "The favorable overall mortality of the study population is a phenomenon commonly observed in working populations. Studies of several occupational groups have shown that, even if there is an occupational hazard which greatly increases the risk of death from a particular cause, the overall mortality may well be favorable," they fail to point out that this usually results from the dilution phenomenon due to the large proportion of short latency workers who have been preselected by various means including preemployment physicals. (Note in Table 6 the deficit of deaths due to cirrhosis of the liver, a disease highly associated with alcohol consumption. Conversation with medical directors of PVC plants have confirmed a preemployment screening for individuals having alcohol

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problems.) This is demonstrated in the author's own Table 12. In the two studies where short latency workers are excluded, thus removing the dilution factor (Tabershaw et al. 1970, and Hammond and Selikoff 1972), Standard Mortality Ratios of well over 100 were found. Furthermore studies conducted by NIOSH have repeatedly demonstrated no excessive risks during the first ten (10) years since onset of exposure followed by highly elevated risks thereafter. This pattern was demonstrable for uranium miners, asbestos workers, coke oven workers, bischloromethyl ether workers, etc. Other mortality studies of vinyl chloride workers undertaken by Mt. Sinai and by NIOSH, indeed, did demonstrate excessive cancer risk and overall mortality risk when consideration was given only to the people having achieved ten or more years since onset of exposure.

Exposure bias in this study was due to the two causes mentioned in the report; time variability and inter-plant variability in estimation of exposure. Due to these variabilities a person who was classified hi exposure at one plant in 1970 may actually have had less exposure than a person classified low at another plant in 1950. Such large variances in this parameter may tend to obscure any dose response curve especially when the two exposure groups are chosen as in the study, those with an Exposure Index less than 1.5 and those with an Exposure Index greater than 1.5. If the study had broken out and compared all

those persons with an Exposure Index less than 1.5 and all those with greater than, say, 2.5, there would be much less overlap and better discrimination between the true high and low exposure groups. Accordingly the current study is biased against demonstrating a dose response relationship.

Lost to follow-up bias occurs when persons whose vital status is determined differ from those whose vital status is not determined in some important characteristic. This study included only those traced and assumed the rest would have similar mortality; however, those persons lost to follow-up were older by an average of ten years, and had longer latencies by an average of 9 years (20 vs 11 years). It is precisely these characteristics of the lost to follow-up group that typify persons in whom carcinogenic effects would be expected to be seen. For example, NIOSH's Office of Health Surveillance and Biometrics has data showing in 1967 among U.S. white males 12% of all deatns among persons less than 45 years of age were due to cancer and approximately 20% of all deaths among persons between 45 and 74 were due to cancer. Thus contrary to the author's opinion, finding these lost to follow-up persons could significantly affect the results of the study.

It is noteworthy that in spite of these bias the TCA epidemiologic investigation did demonstrate that a serious carcinogenic hazard exists following exposure to vinyl chloride. However, based upon the above mentioned bias that investigation undertaken by TCA in its present form

is scientifically unacceptable for any decision making regarding the full extent of carcinogenic response associated with vinyl chloride exposure or regarding a safe level of exposure to vinyl chloride.

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OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION
U. S. DEPARTMENT OF LABOR
Washington, D.C.

| | | |
|---|---|---|
| In the Matter of<br><br>PROPOSED PERMANENT STANDARD FOR OCCUPATIONAL EXPOSURE TO VINYL CHLORIDE | ) | DOCKET: OSH-36 |

SUPPLEMENTARY MOTION OF FIRESTONE PLASTICS COMPANY TO REOPEN HEARING TO PERMIT CROSS-EXAMINATION OF CERTAIN WITNESSES AND TO EXTEND THE TIME FOR FILING COMMENTS TO ADDITIONAL MEDICAL STUDIES

FIRESTONE PLASTICS COMPANY, a Division of THE FIRESTONE TIRE & RUBBER COMPANY, by its attorneys, respectfully moves that the public hearings in the above captioned matter be reopened for the purpose of affording all interested parties an opportunity to cross-examine Dr. Frank Standart and Dr. David Wegman and to refrain from closing the record in these proceedings in order to permit interested parties to submit comments with respect to the statements of Dr. Frank Standart and Dr. David Wegman which are to be filed and made a part of the record in these proceedings. In support of its motion, Firestone states as follows:

1. Firestone reasserts and by reference herein incorporates its Motion to Reopen Hearing to permit cross-examination of all individuals who participated in the design, preparation and writing of the Final Report of Foster D. Snell, Inc.

concerning the economic impact studies of the effects of the proposed OSHA standard for vinyl chloride, which was filed with the Assistant Secretary of Labor for Occupational Safety and Health and the Administrative Law Judge in these proceedings on August 29, 1974.

2. Pursuant to objections to the proposed permanent standard, public hearings were held before the Honorable Gordon J. Myatt, Administrative Law Judge, on June 25-28 and on July 8-11, 1974. Said hearings were closed on July 11, 1974, the record remaining open until August 23, 1974 solely for the submission of general comments and until September 6, 1974 for the submission of specific comments on an economic impact study conducted for OSHA by Foster D. Snell, Inc. (Tr. 1976-1979; 39 Fed.Reg. 30844 (1974)). On September 13, 1974, the time for interested parties to file comments with respect to the final report of Foster D. Snell, Inc. was extended to September 25, 1974, at which time the record in the above proceedings were to be finally closed (39 Fed.Reg. 33009 (1974)).

3. Despite the fact that the record in these proceedings were closed for all purposes with the exception of submitting comments to the Foster D. Snell, Inc. Preliminary and Final Reports, Firestone was advised on September 25, 1974 that OSHA intends to file statements by Dr. Frank Standart and Dr. David Wegman apparently relating to some medical aspect of the issues involved in these proceedings.

4. Firestone objects to the blatant and apparently deliberate attempt to include as a part of the record in these proceedings statements by individuals filed more than one month after the record was closed for all purposes except for receipt of comments to the Snell Preliminary and Final Reports and without either giving all interested parties an opportunity to cross-examine such individuals or to submit written comments concerning such statements.

5. OSHA's conduct in allowing the filing of such statements at this late stage of these proceedings not only contravenes OSHA's procedural rules and regulations, as is more completely set forth in Firestone's Motion to Reopen Hearing, etc., filed on August 29, 1974 (¶¶ 8, 10,11), but also denies the fundamental right of cross-examination to all interested parties as well as an opportunity to comment on the Final Report.

6. Many interested parties, in accordance with the directions of the Administrative Law Judge, as well as in pursuance of the directions promulgated by the Assistant Secretary with respect to the conduct of these proceedings, submitted extensive post-hearing comments on August 23, 1974, the due date for the filing of such materials. The post-hearing comments by interested parties contained substantial comments with respect to the medical and scientific evidence contained in the record in these proceedings and which established conclusively

that there was no medical and scientific evidence supporting either a non-detectable standard or any standard below 50 ppm. Indeed, the medical and scientific evidence dealing with the human experience established that there are no human pathological effects from exposure to vinyl chloride below 200 ppm.

7. All interested parties to these proceedings will be severely prejudiced and deprived of their fundamental rights of due process and of fundamental fairness if they are not accorded the opportunity to cross-examine Drs. Frank Standart and David Wegman and if they are not given an opportunity to submit their comments with respect to the statements filed by these individuals.

8. At a minimum, those interested parties who desire to examine Dr. Frank Standart and Dr. David Wegman should be afforded the opportunity to depose said individuals with respect to the subject matter of their statements so that the same may be included as a part of the record in these proceedings. Such depositions can be quickly arranged and completed so that adoption of a permanent standard by OSHA will not be unduly delayed.

WHEREFORE, FIRESTONE PLASTICS COMPANY respectfully requests that the hearing herein be reopened for the purpose of affording interested parties an opportunity to cross-examine

Dr. Frank Standart and Dr. David Wegman on the subjects contained in their respective reports filed in these proceedings or, in the alternative, that all interested parties be given an opportunity to depose said individuals and that all interested parties be given a reasonable opportunity to prepare and file written comments with respect to the reports filed in these proceedings by said individuals.

Respectfully submitted,

FIRESTONE PLASTICS COMPANY

By _____
John J. Cassidy, Jr.
One of Its Attorneys

WALTER B. CONNOLLY, JR.
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Of Counsel:

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Chicago, Illinois 60603
312/346-5544

Dated: September 26, 1974

## CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Supplementary Motion was mailed by Certified Mail, Return Receipt Requested, on September 26, 1974, to the following:

Honorable Gordon J. Myatt, (Original)
Administrative Law Judge
U.S. Department of Labor
Department of Labor Building
14th and Constitution Avenue, N.W.
Washington, D.C. 20037

Honorable John Stender,
Assistant Secretary of Labor for
Occupational Safety and Health
U.S. Department of Labor
1726 M Street, N.W.
Washington, D.C. 20210

Messrs. Edward Klein and David Kuchenbecker
Office of the Solicitor
U.S. Department of Labor
Department of Labor Building
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Mr. Daniel P. Boyd
Office of Standards Development
U.S. Department of Labor Building
14th and Constitution Avenue, N.W.
Washington, D.C. 20037

Mr. Julius Jimeno,
Hearing Management Officer
Occupational Safety and Health Administration
U.S. Department of Labor
1726 M. Street, N.W. - Room 200
Washington, D.C. 20210

John J. Cassidy, Jr.

LMc/LMc

UNITED STATES DEPARTMENT OF LABOR

Occupational Safety and Health Administration

- - -

INFORMAL FACT-FINDING HEARING ON POSSIBLE HAZARDS OF VINYL CHLORIDE MANUFACTURE AND USE

- - -

The above-entitled matter came on for hearing, pursuant to Notice, at 10:00 a. m.

BEFORE:

GORDON J. MYATT, Administrative Law Judge.

- - -

Conference Room B, Departmental Auditorium
Main Labor Building
14th & Constitution Avenue, N. W.
Washington, D. C.

- - -

Friday, February 15, 1974

- - -

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PRE-HEARING CONFERENCE

JUDGE MYATT: Ladies and gentlemen, we are going to have a pre-hearing conference in this matter concerning the possible hazards associated with the manufacture and/or use of vinyl chloride. The purpose of this pre-hearing conference is to go over with you our proposed order of witnesses, to establish certain ground rules, to verify that those that indicated that they wanted to appear are here and will appear and make a presentation, and to determine which of you who are going to simply present written submissions without oral presentation will do so, and then, finally, at the conclusion, we will start the informal fact-finding hearing.

A large number of you have come considerable distances. We're going to try to accommodate you as much as we can in terms of order of appearance and the time that you're going to have available to you.

The Administrative Law Judge who is presiding over this fact-finding hearing is Gordon J. Myatt, M-y-a-t-t.

We also have representatives from the Solicitor's Office, from NIOSH, and also from OSHA.

To my right and to your left will be the table where the witnesses will appear and make their oral presentation.

This pre-hearing conference is being recorded by our official reporter just as the informal hearing will be

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recorded by the official reporter, and that will be the only official record. Those of you who desire copies of the transcript will have to make your independent arrangements with the reporter or talk to the OSHA people.

I have here a tentative schedule of appearances which has been provided by the OSHA people and I am going to read at this point the order in which the witnesses are scheduled thus far.

Once we open the informal hearing, we are going to have a brief submission of exhibits from the representative of the Solicitor's Office into the record, and then we will have the first presentation. Mr. John O'Neill, Chief of the Division of Health Standards of OSHA, has requested approximately five minutes.

The second witness will be Mr. Vernon E. Rose, Acting Assistant Institute Director for Research and Standards Development of NIOSH, and he will be on for approximately 15 minutes.

The third witness will be Prof. Cesare Maltoni from Italy, and his presentation, I understand, will take approximately 45 minutes.

Dr. Maltoni will be followed by B. F. Goodrich's representatives.

We understand that Dr. Irving Selikoff from the Mount Sinai School of Medicine has requested approximately 20

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minutes. He is flying in here -- pardon me -- I hope this isn't indicative of the way the day is going to go. We've already made changes on it.

After Mr. Vernon Rose, who I indicated would be on second, we're going to have Dr. Irving Selikoff from the Mount Sinai School of Medicine. It has been indicated that he is present. He will be on for approximately 20 minutes and he will be followed by Mr. Anthony Mazzocchi, the Legislative Director of the Oil, Chemical and Atomic Workers International Union.

Is Mr. Mazzocchi here?

MR. MAZZOCCHI: Here.

JUDGE MYATT: Mr. Mazzocchi will be followed, then, by Prof. Maltoni, who will have approximately a 45-minute presentation.

After Prof. Maltoni, we have Mr. A. C. Clark, the Vice-President and Technical Director of the Manufacturing Chemists Association.

Is Mr. Clark here?

Following Mr. Clark, then we will have the B. F. Goodrich presentation.

The next order of witnesses starts with Mr. Sheldon Samuels, the Director of the Health, Safety and Environmental Affairs of the Industrial Union Department of the AFL-CIO, who, I understand, will be introducing Dr.

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Henry Anderson of the Mount Sinai School of Medicine and Dr. Thomas F. Mancuso of the University of Pittsburgh Graduate School of Public Health and possibly Mr. Peter Bommarito or Mr. Louis Beliczky, who is the Director of Industrial Hygiene for the United Rubber Workers. And then we will go -- they are going to take approximately 60 minutes.

And then that presentation is scheduled to be followed by Dr. V. K. Rowe, toxicologist, Dow Chemical, who has requested approximately 30 minutes, followed by Mr. Herbert K. Carver, Jr., of Dove Packaging Systems, who has requested ten minutes.

Mr. Richard J. Reynolds, representing Shell Chemical Company, will follow and he has requested approximately 20 minutes, and Mr. Donald Holman of Control Data Corporation has requested ten minutes and will follow Mr. Reynolds.

And Dr. Robert Brookman of Firestone is tentatively scheduled as our last witness, and he has requested ten minutes.

I have just been informed that this tentative order of appearance will be typed up and Xeroxed for you so everyone can have a copy.

Now, are there any other individuals, before we proceed, who have desired to make an oral presentation and have not registered with our folks here in the back?

I'm going to assume by your silence, then, that

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everyone who is going to make a presentation has been registered and has been scheduled.

I might toss this out during this pre-hearing conference for your consideration, that those of you who have your presentation typed and written, should you desire simply to make a submission rather than to give your oral presentation, we would certainly be amenable to that. It would save time -- and it would certainly be in the record, but I don't want to preclude anyone from making an oral presentation if they so desire.

One other thing to be considered now is that under the rules and regulations all exhibits must be in triplicate. So if you're going to make a submission, please have three copies available, or if you don't have three copies available, let's make arrangements for you to get duplicates made of the copy that you're going to submit.

I will also indicate to you at the conclusion of the informal hearing the date until which we will determine to keep the record open so that if you have any further submissions you will have ample time to get them in. We will set that date after a conference with the OSHA people and the Solicitor's representative.

At this point I think the only thing left is to ask if any of you have any questions concerning procedures that we may not have touched upon or any other questions that you

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want to take up at this point before we get into the informal hearing.

If not, we will take a brief recess and we will start promptly at 10:00 -- oh, one other thing before we start. We're going to strictly enforce the no smoking rule in this room.

(Whereupon, at 9:45 a. m., the pre-hearing conference in the above-entitled matter was closed.)

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PROCEEDINGS

JUDGE MYATT: The hearing will be in order.

This is an informal fact-finding hearing which is being conducted to give interested persons or organizations an opportunity to present oral or written data, views and/or positions regarding the possible hazards associated with the manufacture and/or use of vinyl chloride.

Notice of this fact-finding hearing was published in Volume 39, No. 21, of the Federal Register on January 30th, 1974, pursuant to the Occupational Safety and Health Act of 1970.

As I indicated during the pre-hearing conference, the Administrative Law Judge presiding at this hearing is Gordon J. Myatt.

It's my function to regulate the course of these proceedings, dispose of any procedural requests and objections, and confine as much as possible the presentations to matters pertinent to the requested information, and, in the exercise of my discretion, determine the extent of any questioning of any witnesses appearing here.

In this regard, I am going to limit the questioning to those individuals or persons representing those organizations who have registered here to give oral presentations. I am not restricting the questioning to the specific individual who is named as the person giving the presentation for a

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given organization. In other words, Shell Chemical is listed here and Mr. Richard J. Reynolds is the one who is going to give the presentation. It need not be Mr. Reynolds asking questions if Shell desires to ask question of any witnesses. Any of the representatives of that organization may ask the questions.

I would suggest, however, in order to expedite these proceedings, that you decide among you of any given organization of company who will be your spokesman. That is a matter for you, who will ask these questions.

I will not, however, allow questions from the floor of any of the witnesses from any individuals who have not signed up here to give an oral presentation.

I also wish to stress at this time that it is not my function to pass on the evidence or the presentations made here; rather, upon the close of this informal hearing and after the receipt of any written data or documents submitted within the time which I shall specify at the time we close, I will certify the complete record to the Assistant Secretary of Labor, Occupational Safety and Health, for his action.

Yes, sir?

DR. JAEGER: Dr. Rudolph Jaeger, Assistant Professor of Toxicology, Harvard School of Public Health.

Your previous ruling excludes me from asking questions of any witness. I am not associated with any group

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but I feel qualified to judge or comment on the scientific merit of information presented here. Am I specifically excluded, sir?

JUDGE MYATT: Yes, sir.

Yes, ma'am?

MS. HRICKO: Andrea Hricko, Health and Research.

If I'm also excluded under that rule, I'd like to know on what grounds that decision was made.

JUDGE MYATT: The grounds are that in order to get these proceedings over with and to get the evidence in the record, we cannot allow questioning from people who are not listed here for oral presentation.

Now, if I may continue, as I indicated during the pre-hearing conference, the official reporter makes the only transcript of these proceedings and all oral presentations and examinations will be recorded by the reporter. Copies of all written submissions and documents received in the record and the official transcript will be maintained by OSHA in Room 240 at 1726 M Street, N. W., Washington, D. C.

And, again, any person or persons desiring to purchase a copy of the official transcript should make their own arrangements directly with the reporter.

We have also had a request from our technical people to remind you that when you're up here testifying, these microphones are not the most sensitive, and, therefore,

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we would ask you to speak directly into them because your volume may fade.

We are going to proceed with the informal hearing by first allowing the representative of the Solicitor's Office to introduce certain documents, and then we will proceed with the order of witnesses that I indicated previously during the pre-hearing conference.

MS. GHOLSTON: My name is Evelyn Gholston. I am an attorney from the Solicitor's Office for the Department of Labor.

As Exhibit No. 1 I would like to introduce a copy of the Federal Register notice of the fact-finding hearing on the possible hazards of vinyl chloride manufacture and use which was published on January 30th, 1974, at 39 Federal Register 3874.

JUDGE MYATT: It will be received as Exhibit No. 1.

(Whereupon, Exhibit No. 1 was marked for identification and was received in evidence.)

MS. GHOLSTON: As Exhibit No. 2, I would like to introduce the following notices of intention to appear. The first notice comes from the B. F. Goodrich Company.

JUDGE MYATT: We will classify that as 2(a), and the others alphabetically.

MS. GHOLSTON: The next notice will be 2(a). It's from Vedder, Price, Kaufman & Kammholz, and it's notice of

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intention of Firestone Tire & Rubber Company.

JUDGE MYATT: That's 2(b). The first one, B. F. Goodrich, is 2(a).

MS. GHOLSTON: I'm sorry. B. F. Goodrich will be 2(a) and Firestone will be 2(b).

2(c) would be for The Dow Chemical Company.

2(d) would be from the Oil, Chemical and Atomic Workers International Union for Dr. Irving Selikoff.

2(e) would be from the Oil, Chemical and Atomic Workers International Union, also, for Mr. Anthony Mazzocchi.

And 2(f) is from Wayne T. Brooks, Director of Occupational Safety & Health Services -- excuse me. Mr. Brooks is from the Organization Resources Counselors.

We've just received another notice from the Shell Chemical Company, and that will be 2(g).

JUDGE MYATT: Does that conclude it?

MS. GHOLSTON: That's all.

JUDGE MYATT: All right. Exhibits 2(a) through 2(g) will be received in the record.

(Whereupon, Exhibits Nos. 2(a) through 2(g) were marked for identification and were received in evidence.)

JUDGE MYATT: At this point, then, we will proceed with our scheduled order of witnesses.

Mr. John O'Neill, Chief, Division of Health

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Standards of OSHA.

JOHN O'NEILL

MR. O'NEILL: Mr. Standard, the Assistant Secretary of Labor for Occupational Safety and Health, recognized that a health problem was developing in those areas that used vinyl chloride or manufactured polyvinyl chloride.

In order to develop a posture to determine what the Occupational Safety and Health Administration will do in this case and in order to determine what rule-making should be accomplished, this meeting for fact-finding has been arranged.

I want to emphasize there is no proposal to be discussed. This is simply, we hope, a meeting that will develop the data and the information necessary for OSHA to act.

The notice of the hearing outlines succinctly the type of information that we feel would be most important for our deliberations. These include discussions of the data on the toxicity on the chemicals in question, the technologies involved in their manufacture and use, the employee populations potentialy at risk, epidemiological data indicating the impact of these chemicals upon the work populations, and further information as to the acuteness of this hazard in order to determine whether it should be best handled by an emergency standard or by normal rule-making.

With these few words, I hope that I have put in the

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proper perspective the reasons for this fact-finding group. We hope it will be very fruitful.

JUDGE MYATT: Thank you, Mr. O'Neill.

The next scheduled witness is Mr. Vernon E. Rose, Acting Assistant Institute Director for Research and Standards Development, National Institute for Occupational Safety and Health, known as NIOSH.

VERNON E. ROSE

MR. ROSE: Good morning. I am Vernon E. Rose, Acting Assistant Institute Director for Research and Standards Development of the National Institute for Occupational Safety and Health, or NIOSH, a program of the Center for Disease Control in the Department of Health, Education and Welfare.

We have a statutory responsibility under the Occupational Safety and Health Act of 1970 to, and I quote, "...develop and establish recommended occupational safety and health standards." These recommended standards are then made available to the Occupational Safety and Health Administration in the Department of Labor and serve as the basis for the setting of occupational safety and health standards.

On July 17th, 1973, a meeting was held with certain representatives of the Manufacturing Chemists Association, or the MCA, and members of the NIOSH staff at the request of the MCA. At this time the MCA informed NIOSH of a proposed

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research study to be conducted by an independent laboratory involving the exposure of several rodent species to vinyl chloride vapors at concentrations including 50, 500, and 5,000 parts per million.

The experimental protocol was to include statistically significant numbers of animals of each species including both sexes. The exposure protocol was to be compatible with a normal work week and the duration of exposure and subsequent observation was to be compatible with the normal lifespan of the particular species. Histologic examination of all major organs was to be included and special attention was to be given to behavioral changes and manifestation of lesions.

It is anticipated that the results of this study will be available in eighteen to twenty-four months from the present time.

At the meeting the MCA representatives reviewed the pertinent published accounts of toxicity and tumorigenicity associated with vinyl chloride, including the work of Prof. P. L. Viola published in 1970 and in 1971. Prof. Viola demonstrated the induction of tumors in the skin, lungs, and bone of rats exposed to vinyl chloride at a very high concentration, that is, 30,000 parts per million. He did not find tumors of the liver.

The NIOSH staff considered the proposed study to be

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of excellent design and requested the MCA to keep them advised of the ongoing study as appropriate.

Earlier, on January 30th, 1973, NIOSH had published a request in the Federal Register for information concerning potential hazards associated with occupational exposure to 23 chemical substances and physical agents. Vinyl chloride had been included in this request.

As a result of this Federal Register request and additional independent literature searchers by NIOSH, a bibliography consisting of the pertinent literature has been assembled. Any literature not currently available in NIOSH is being retreived. This bibliography, along with copies of all cited references, will be transmitted to the Department of Labor.

On January 22nd, 1974, representatives from the B. F. Goodrich Chemical Company informed NIOSH that the deaths of several employees of their Louisville, Kentucky, plant might have been related to occupational exposures. Had not the company taken the initiative it did in following up on suspicions aroused by the occurrence of the rare type of liver cancer, that is, angiosarcoma, discovered in several of its employees at autopsy, it is entirely possible that the significance presently attached to the appearance of these tumors would not have been realized for several more years.

As a result of this information, a walk-through

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survey was conducted on January 24th in the company's facility in Louisville by NIOSH. Also participating in the survey at the specific request of NIOSH were representatives from the Department of Labor of the State of Kentucky, the Occupational Safety and Health Administration of the U. S. Department of Labor, and the Epidemic Intelligence Service of the Center for Disease Control.

As a result of the walk-through survey, NIOSH recommended on January 30th, 1974, that certain monitoring and control procedures of a precautionary nature be instituted at the Louisville facility. A copy of this communication is included as Attachment 1.

On the following day NIOSH also recommended to the MCA that similar precautionary measures be instituted at all facilities engaged in the polymerization of vinyl chloride and requested that MCA disseminate this information to such companies. A copy of this communication is also included as Attachment 2.

On February 1st, 1974, NIOSH and CDC held a briefing for other federal agencies with health research responsibilities, including the National Cancer Institute, the Food and Drug Administration, the National Institute of Environmental Health Sciences, and the Environmental Protection Agency. Also attending the briefing were professional representatives of the Kentucky Department of Labor, the B. F. Goodrich

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Company, and the United Rubber Workers Union.

The briefing involved the medical, epidemiologic, toxicologic, and industrial hygiene findings thus far obtained, and it was concluded that a new occupational cancer had been discovered, that is, angiosarcome of the liver. It was further concluded that this disease was associated with the polymerization of vinyl chloride in the manufacture of polyvinyl chloride and that vinyl chloride was suspected as the prime etiologic candidate among the more than 50 chemicals used in the Louisville, Kentucky, facility. It was announced at the briefing that NIOSH would institute a series of animal toxicological studies in concert with the National Cancer Institute and accelerate an industry-wide epidemiological study.

Currently, it is estimated that ten companies with fourteen plants and more than 1,500 production workers are involved in producing vinyl chloride monomer. It is further estimated that some 23 companies and 37 plants employing more than 5,000 production workers are involved in the polymerization of vinyl chloride to polyvinyl chloride. It is difficult to estimate the number of workers employed in converting, molding, and fabricating the polymers into finished products, but it is in the order of tens of thousands working in thousands of plants throughout the country. These estimates are based primarily on manufacturing data obtained from the

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1973 edition of the Chemical Economics Handbook published by the Stanford Research Center.

It was disclosed at the NIOSH/CDC briefing that four employees from the Louisville facility of B. F. Goodrich Company had died of angiosarcoma of the liver. Autopsy and/or biopsy material from each of the deceased employees was still available; therefore, an epidemiologist from the Center for Disease Control obtained specimens and slides for independent histologic confirmation of the diagnosis by pathologists at the Clinical Center, National Institutes of Health. In each of the four cases the diagnosis of angiosarcoma of the liver was confirmed. In addition, each of the four liver specimens presented a common nonalcoholic cirrhosis of the liver. A report of the occurrence of angiosarcoma of the liver among polyvinyl chloride workers appearing in the current CDC Morbidity and Mortality Weekly Report is included as Attachment 3.

NIOSH has investigated the number of deaths attributable to angiosarcoma of the liver in the United States and considers the occurrence to be on the order of twenty to thirty each year. It is because of the extremely low incidence of deaths attributable to this disease that the clustering of four cases within a five-year period in the Louisville, Kentucky, facility has been of such great importance.

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During the federal agency briefing, NIOSH and other official agencies were advised by a B. F. Goodrich Company representative as to the status of an ongoing study sponsored by European polyvinyl chloride producers and involving the exposure of small groups of rats to vinyl chloride monomer vapor. Although the results reported were only of a preliminary nature, NIOSH considers that these data, which include histopathologic examination of tissue, identify vinyl chloride monomer as the causative agent in the induction of tumors observed in the test animals, including angiosarcoma of the liver. NIOSH has been advised that the principal investigator responsible for conducting the European studies, Prof. C. Maltoni of Italy, intends to present the results of his investigations to the Occupational Safety and Health Administration during this public hearing.

On February 12th, 1974, NIOSH sponsored a briefing for management and labor representatives from the vinyl chloride and polyvinyl chloride industries. The meeting was held in Cleveland, Ohio, and was attended by approximately 100 individuals. The briefing was conducted by members of the NIOSH and CDC staffs who presented information obtained up to that time concerning the hazards of occupational exposure to vinyl chloride during the polymerization process.

Following review of the problem, NIOSH presented plans for future activities including, number one, development

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of recommended standards; number two, medical surveillance and research programs; number three, industry-wide epidemiologic studies; and, number four, additional toxicologic investigations.

Development of the recommended standard commenced immediately following the NIOSH briefing when members of the NIOSH and CDC staff met with a small group of expert advisors selected from both industry and labor. The purpose of this meeting was the review of the precautionary procedures previously recommended to polyvinyl chloride producers. NIOSH anticipates that such recommendations will be transmitted to the Department of Labor in a few weeks.

Summaries of proposed NIOSH and CDC plans for epidemiologic, medical, and toxicologic studies are included as Attachment 4.

That concludes our formal presentation, and I do have three copies of the presentation to submit.

JUDGE MYATT: All right. The presentation will go into the record as Exhibit 3.

(Whereupon, Exhibit No. 3 was marked for identification and was received in evidence.)

JUDGE MYATT: Are there any questions to be asked of Mr. Rose by those who are going to make oral presentations?

MS. GHOLSTON: Mr. Rose, you mentioned that you made some recommendations to B. F. Goodrich for monitoring. Did

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you recommend any specific type of monitoring?

MR. ROSE: As to the question of whether or not NIOSH recommended specific types of monitoring for materials and hazards in the plant, we recommended that both environmental and personnel sampling be conducted for both vinyl chloride monomer exposure, which would be in the gaseous state because of the pressure of the gas, and, secondly, that measurements be taken for exposures to polyvinyl chloride dust. We did not recommend specific analytical or sampling procedures, but we did indicate that certain staff members of NIOSH in Cincinnati would be available to provide consultation as to appropriate sampling procedures.

MS. GHOLSTON: Thank you.

JUDGE MYATT: Are there any other questions?

Sir, would you identify yourself for the record?

MR. CONNOLLY: My name is Walter B. Connolly, Jr., and I'm labor counsel for Firestone Rubber Company.

Mr. Rose, I'd like to ask you whether or not it is NIOSH's recommendation that standards be implemented in this area pursuant to the regular rule-making procedures provided under Section 6(b) of the Occupational Safety and Health Act.

MR. ROSE: NIOSH considers the situation that has developed in the Louisville facility of B. F. Goodrich to be extremely serious and, indeed, our reaction to the information as presented to us was one of, you might consider, almost a

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crisis response on our part, in that we did send a field team into the plant to observe conditions there, and we have also considered and will implement the studies that I further defined, studies of a research nature.

I am assuming and feel that when we transmit our recommendation to the Department of Labor they will stress a high sense of urgency that rule-making be commenced -- that rule-making be conducted.

MR. CONNOLLY: Thank you.

JUDGE MYATT: Any further questions of this witness? There being none, thank you, sir.

Our next witness is Dr. Irving J. Selikoff, Director of Environmental Scienes Laboratory, Mount Sinai School of Medicine.

DR. IRVING J. SELIKOFF

DR. SELIKOFF: My name is Dr. Irving J. Selikoff. I'm a Professor of Medicine and Professor of Community Medicine at the Mount Sinai School of Medicine of the City University of the City of New York and Director of its Environmental Sciences Laboratory.

First, I think that this hearing is somewhat of a paradox. Rapidly organized, with an emergency standard being requested, one would imagine that a new, serious problem had been identified and that we are responding to it, and this is partly true. However, equally true is that there has been

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evidence of potentially serious disease among workers engaged in vinyl chloride-polyvinyl chloride manufacture for 25 years which has, for reasons not yet well understood, been incompletely appreciated and inadequately approached by medical scientists and by regulatory authorities. In other words, this is not a new problem. What is new is the vigor and extent of our attention to it.

Thus, for example, acute animal toxicity to vinyl chloride was reported as long as ago as 1938 and important chronic toxicity in 1961. Even more, we didn't need the animal studies to warn us that workers could be harmed in VC-PVC manufacture. As far back as 1949, 25 years ago, liver damage was found in 15 of 48 workers in Russia and disease of liver, skin, and other organs was reported in the next 17 years, not only from Russia but from France and Romania as well. In 1966 and 1967 attention was called to still another lesion, acroosteolysis, an affection of the skin and bones of the hands and feet, and further reports of hypertension, vascular lesions, nervous system and kidney damage and scleroderma later appeared.

Therefore, we have had ample warning that cells, tissues, and organs could be badly damaged during VC-PVC production. Despite this, our approach to the problem, as I said, seems to have been somewhat leisurely.

And we are now galvanized into action. Why?

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Evidently, by the sudden discovery, as Mr. Rose has demonstrated, that VC-PVC exposure cannot only damage, scar or destroy tissue in the liver, bone, nervous system, kidney, and other organs, but that neoplasms can also result.

This change in attitude is fully understandable. Not only is the disease, cancer, more serious, but, once initiated, it is irrevocable and often inexorably fatal.

And, thus, we have a new problem, not merely one in which level of exposure will produce this or that extent of liver cell or skin damage, which could be reversed if our estimates are wrong, but, rather, the question of cancer, an irreversible disease where we can't afford to be wrong.

Now, the cancer that has been identified is one of the type which, unfortunately, is progressive and invariably fatal. Approximately 100 are known to have occurred in medical history. Not one has been cured.

Hemangiosarcoma of the liver has in the past been extraordinarily rare. At the Los Angeles County Hospital only one instance was found in 52,000 consecutive autopsies. Our own experience is similar. At one of the institutions of the Mount Sinai Medical Center, Elmhurst General Hospital, no case has been seen despite the very active medical and surgical services of this thousand-bed hospital. In another of our institutions, the Bronx Veterans Administration Hospital, no case has been seen, despite a search of our files, in 30,000

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consecutive autopsies and 200,000 surgical specimens since 1941. Yet four cases have been described in one vinyl chloride-polyvinyl chloride plant in the United States in which some 250 workers are employed in the VC-PVC operation. This is an extraordinary increase in incidence.

At the same time we should recognize that we know very little yet about the carcinogenic potential of exposures during VC-PVC operations. For example, it is not known whether the hemangiosarcomas will affect only the liver. When this tumor results, let us say, from thorotrast injection, which it can, other tissues and other organs such as bone marrow can be involved. Indeed, we do not know whether hemangiosarcoma will be the only neoplasm associated with exposure in such circumstances.

Experimentally, Viola, with very heavy exposures, has demonstrated that specific skin cancer and cancers of the lung occurred in the animals studied. Experience with other carcinogenic agents has taught us that when a material causes cancer in one organ, it often does in other tissues as well.

On the other hand, in the very short time that has elapsed since we have been alerted to the cancer problem, we have made two key observations. First, just as liver and other organ disease may be found throughout the VC-PVC production industry, hemangiosarcoma will not be restricted to one plant, since it is known that this tumor has also been

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found in Great Britain as well.

A second, even more worrisome observation, has been that the latent period between onset of exposure to the agent and clinical evidence of disease is a long one. The Louisville tumors appeared in workers 14 to 27 years from the onset of their work exposure. This resembles the latent period of thorotrast-induced hemangiosarcoma of the liver where the average latent period has been 21 years. Therefore, uncontrolled exposures in the past are likely to be reflected in the occurrence of tumors in the decades ahead, unless we can learn to reverse the carcinogenic process already presumably underway in the workers involved.

The discovery of vinyl chloride-polyvinyl chloride associated cancer gives added reason for urgent concern, since the tumor joins other serious burdens of such exposure.

Recent studies in Germany have shown that liver damage is far more common and far more serious than we had hitherto expected. Marsteller and his colleagues reported ten weeks ago that in a careful study of 20 workers in a PVC-producing plant, with a range of exposure of from one and a half to twenty-one years, nineteen -- nineteen out of the twenty has some evidence of liver disease, including gross changes of liver and spleen by direct inspection at laparoscopy in fourteen. They operated on these people and in fourteen out of the twenty cases direct inspection of the

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liver and spleen showed disease to be present. Since acro-osteolysis was present in only four, and since enlargement of the liver could be felt by physical examination only in six, it is evident that these gross clinical tests may seriously under-read the extent of liver damage.

In our own studies of a small number of workers of the Goodyear plant in Niagara Falls, we have similarly seen liver changes. We have also found lung changes to be important. These have previously been described and require rapid and careful study.

An important point to make is that we still know very little about the long-term, chronic effects on the various important organs of the body, when they occur and when they don't occur. The occurrence of cancer should not obscure potential damage of serious non-neoplastic disease as well.

I would, therefore, urge that the Department of Labor take immediate measures to control exposures of workers engaged in VC-PVC operations. I have a number of recommendations to suggest which I believe will facilitate such control.

First: Vinyl chloride-polyvinyl chloride exposure should be added to the list of carcinogens promulgated by the Department. It is evident that no threshold is known that would serve to prevent cancer among exposed workmen. Therefore, carefully designed work practices and procedures should

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be identified to govern VC-PVC production. In this regard, we have been impressed, and I'm sure you have been also, with the approach of NIOSH to this aspect of the question so far. Further, it is clear that industry know-how and expertise will be most valuable in the development of the necessary work practices and procedures.

2. The guiding rule for the workers concerned, above and beyond the specific work practices to be developed, should be that no further exposure occur by any route, inhalation, contact or ingestion.

3. It has been pointed out above that we still know comparatively little about the cancer problem and even about the question of chronic organ damage. Therefore, large-scale epidemiological and clinical studies should be mounted as rapidly as possible to determine the full extent and nature of the hazard. These should be broad studies, long-term, generously conceived, and designed to allow us the opportunity for surprises, because we may get some additional surprises.

4. Research should be begun immediately to develop early diagnostic techniques for VC-PVC associated tumors. In this we may have the advantage of knowledge that liver damage will occur before the initiation of the cancer process. Therefore, early diagnosis of VC-PVC disease in general should be looked to, including disease of the lung, skin,

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thyroid, nervous system, liver, kidney, and bladder.

5. It would also be desirable to develop early methods of diagnosis of the tumor, even after it has been initiated. Since it is a vascular neoplasm, it may be that some of our newer techniques of radioactive scanning will allow for such early detection.

6. Simultaneously, programs of therapy should be developed. For example, liver experts should be recruited to look at reversal of liver disease that may occur. Even serious liver disease can sometimes be treated in these patients. We have seen one successful utilization of portal-caval shunts, and we are aware of three others. Similarly, the possibility of the treatment of associated tumors should be investigated as intensively and rapidly as possible.

7. Such early diagnosis and treatment would be expedited and advanced if basic mechanisms of damage could be defined. Here, scientists associated with the National Institute of Environmental Health Sciences could be asked for help.

8. Similarly, the disciplines of experimental toxicology and experimental pathology should be utilized to undertake studies of a basic nature of a different sort. As yet we are uncertain as to which agent or agents are responsible for the toxic and neoplastic effects associated with VC-PVC manufacture. I do know that NIOSH, as Mr. Rose has

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said, considers that vinyl chloride is the heavily suspected agent. We are not sure of this, in my opinion, and I think we should keep an open mind that other agents may be found to be responsible. Therefore, it may be well that laboratory investigations, in addition to epidemiological studies, will make it possible to sort out the effects of various materials and agents.

9. The full extent of the occupational problem should be defined as an urgent matter: are workers exposed to vinyl chloride or polyvinyl chloride in the manufacture of products containing them at risk? We don't know that at this point. In studies to determine the extent of the occupational problem, we can make good use of biochemical and clinical markers, including changes in blood enzymes, clinical findings, lung changes, et cetera.

Now, it may be noted that my recommendations refer to vinyl chloride-polyvinyl chloride production. I have been asked whether regulation should also be promulgated to cover occupational use other than in such production or to consumer products. I would not now recommend this. Our knowledge of health effects is limited to vinyl chloride-polyvinyl chloride production. Now, we should rapidly study whether health effects will be associated with end product or consumer use. Data obtained can then be used to judge whether other

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regulations are needed.

It may turn out that the biological effects are limited to agents present only in vinyl chloride-polyvinyl chloride production. Hopefully this is going to be so, but we don't know.

Now, this meeting takes place at a very solemn moment. In a sense, it not only marks our determination to confront and control a very serious occupational health problem, but it also marks a failure on our part -- failure to protect workers who have every right to expect that scientists, industry, and governmental agencies would protect them against known or suspect hazards. This we failed to do. As a result, what Dr. David P. Rall has called "invisible pollution" associated with what he has called "a new industrial revolution, based on the chemical-process industry," is now becoming visible in terms of disease and death. Our task here today is to address this and to insure that it go no further. No effort should be spared and no control considered too rigorous.

JUDGE MYATT: Thank you, Dr. Selikoff.

Are there any questions of Dr. Selikoff?

MS. GHOLSTON: Yes, I have one.

Dr. Selikoff, you said that there was no known exposure limits. Could you recommend any exposure limits for employees working with PVC and vinyl chloride production?

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DR. SELIKOFF: I could recommend no exposure limits for the prevention of cancer among these workers. There is none known at this time.

MS. GHOLSTON: You mentioned with reference to end products, consumer products, that you would not recommend anything at this time. Are you familiar with any effects of polyvinyl chloride in the end-product stage? For instance, in the meatpacking industry.

DR. SELIKOFF: I have heard reports of this. I have spoken to workers who claim this, but our own studies are not yet at a stage where we can say whether or not the same effects seen in polyvinyl chloride or vinyl chloride workers are seen in the meatcutting industry, the extrusion industry, et cetera.

I think such data are badly needed and should be obtained as rapidly as possible, but at this point in time we should be prudent and limit our activity and judgment to what we already know in the data now at hand.

MS. GHOLSTON: Thank you.

JUDGE MYATT: Are there any further questions? There don't seem to be any.

Thank you, Dr. Selikoff.

Our next speaker making a presentation is Mr. Anthony Mazzocchi, Legislative Director of the Oil, Chemical and Atomic Workers International Union.

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ANTHONY MAZZOCCHI

MR. MAZZOCCHI: My name is Anthony Mazzocchi; Legislative Director of the Oil, Chemical and Atomic Workers Union.

A new occupational carcinogen has been discovered. Thousands of workers throughout the United States are currently exposed to this carcinogen. The responsibility of the Labor Department is clear. An emergency temporary standard must be promulgated immediately.

We have studied the evidence that has been made available and we have concluded that vinyl chloride is a carcinogen. For further analysis on this point we refer you to the testimony presented here today by Dr. Irving Selikoff of the Mount Sinai School of Medicine and Dr. Thomas Mancuso of the University of Pittsburgh.

The fundamental purpose of the Occupational Safety and Health Act is to assure every working man and woman in the nation safe and healthful working conditions and to preserve our human resources. In order to satisfy this Congressional mandate, the Secretary of Labor was delegated the authority under Section 6(c)(1) to establish "...an emergency temporary standard to take immediate effect upon publication in the Federal Register if he determines, (a), that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new

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hazards and, (b), that such emergency standard is necessary to protect employees from such danger..."

Therefore, the criteria for granting an emergency standard rests on a twofold evaluation involving a demonstration of a grave danger from exposure to the particular chemical and the necessity of a regulation to afford protection.

It is clear beyond a shadow of a doubt that these two criteria have been met in the case of vinyl chloride. A grave danger exists from cancer, yet industry has failed to protect its employees.

Therefore, the Oil, Chemical and Atomic Workers International Union joins with the Industrial Union Department of the AFL-CIO and hereby petitions the Occupational Safety and Health Administration for an emergency temporary standard on vinyl chloride.

We concur with the IUD that the basis for such a standard must come from the recommendations of the Standards Advisory Committee on Carcinogens that were submitted to the Labor Department on August 27th, 1973.

While these recommendations were developed for a standard on fourteen specific carcinogens, the foundation upon which the Committee based the recommendations is sound for other occupational carcinogens, including vinyl chloride.

Briefly, we would like to highlight some of the

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Committee's recommendations because of their special relevance today:

1. The principle of no measurable exposure or contact by any route, oral, respiratory or skin, to a carcinogen; the use of the most sensitive, feasible, approved, reliable methods of environmental and personnel monitoring; and the ultimate objective of no exposure.

2. Prohibition of open-vessel operations.

3. Providing of all work clothing, protective equipment, and clothing, and work and shower supplies, including towels, by the employer.

4. Extensive requirements for safe work practices, emergency procedure, and training and education.

5. Forwarding of employee medical records to NIOSH upon termination of employment or cessation of business by employer.

6. Confidentiality of medical records.

7. Endorsement of a use permit system as an integral part of the standard.

The Advisory Committee had also planned to develop specific criteria for medical examinations, but it fell short of time. However, such criteria that is applicable to vinyl chloride exposure has been developed by Dr. Henry Anderson, Clinical Consultant to the IUD. We endorse Dr. Anderson's criteria and we request that it be made part of the emergency

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temporary standard.

You may hear testimony today from industry representatives who claim that there is no further verification in their plants of what happened at Louisville. They may also claim that their employees, in any case, are fully protected and, thus, no new standard is needed.

We are skeptical of these opinions. First, we have learned that a recently issued set of NIOSH recommendations on control procedures for vinyl chloride is not being adhered to by the industry. Direct exposure to vinyl chloride still occurs in processing and maintenance operations. You may also hear of industry claims of outdoor operations and so-called "closed processes" that minimize employee exposure. On the contrary, we have found that throughout the chemical industry that these outdoor "closed" processing units allow for considerable exposure to workers from leaks, spills, ruptures, and maintenance work.

Second, industry representatives may site the lack of any epidemiological evidence in their plants as proof that Louisville was an isolated occurrence. One PVC manufacturer, Air Products and Chemicals, Incorporated, at their Calvert City, Kentucky, plant has done just that in a recent 14-page letter to their employees. Air Products failed to tell its employees that the latency period for development of angiosarcoma, from the beginning of exposure to diagnosis of the

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disease, is suspected to be in the neighborhood of 15 years. This Air Products plant, however, is only ten years old and, thus, cancer cases should not be expected until another five or so years have passed. Furthermore, the inherent shortcomings in the use of death certificates in developing epidemiological data must also be understood. Death certificates are well-known to provide false negatives. This is particularly true with angiosarcoma of the liver, which is so rare in the United States that doctors may misdiagnose it. Also, angiosarcoma may have been present at the time of death but may not have been the primary cause of death. These omissions and others point out the shortcomings of relying solely on studies of death certificates to disprove epidemiological experience with angiosarcoma.

We have begun a study of Oil, Chemical and Atomic Worker plants to determine how many make or use vinyl chloride. Initially, we have found several plants and a considerable number of employees involved.

In one of our vinyl chloride polymerization plants, Dr. Irving Selikoff of the Mount Sinai School of Medicine has recently examined a number of workers. His results included gross findings indicative of liver disease and acroosteolysis. These positive findings are an extension of what has been found at the B. F. Goodrich plant in Louisville. These findings further prove that the occupational hazard from vinyl

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chloride is an industry-wide problem.

It is sad to note that only eight months ago the magazine of the plastics industry, Modern Plastics, June 1973, labeled reports of recent animal studies in Italy which found "a disproportionate incidence of skin and organ cancer" as "scare stories." Because of such an industry attitude, OSHA must act by issuing an immediate emergency standard to protect workers.

What we know about the relation between cancer and vinyl chloride is only the tip of the iceberg because of the long latency period. But OSHA can act now to prevent such a carcinogen from being further present in the work environment. Such a standard must eliminate worker exposure to vinyl chloride. There is no known safe or allowable exposure when dealing with a carcinogen. A committee of eight cancer scientists which evaluated the risks of chemical carcinogens for the U. S. Surgeon General in 1970 sharply challenged the concept of a safe dose. "It is impossible," they said, "to establish any absolutely safe level of exposure to a carcinogen for man."

Today, somewhere in the United States a worker is being exposed to vinyl chloride that will someday cause him cancer and a slow, painful death. The Labor Department thus far has responded commendably to this emergency by calling for this hearing within three weeks of its discovery.

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We now ask you to follow through with your responsibilities by issuing and enforcing an emergency temporary standard on this carcinogen.

JUDGE MYATT: Thank you, Mr. Mazzocchi.

Before we go further, we're going to make a change in the so-called updated list which you got. There's a substitution. You'll see No. 12, Mr. Wayne T. Brooks of the Organization Resources Counselors. He has been deleted, and in his place has been substituted Prof. Rudolph J. Jaeger, Department of Physiology, Kresge Center for Environmental Health, Harvard School of Public Health.

In addition, Mr. Mazzocchi, your submission will be Exhibit No. 5.

(Whereupon, Exhibit No. 5 was marked for identification and was received in evidence.)

JUDGE MYATT: For the record, Madam Reporter, Dr. Selikoff's submission is Exhibit No. 4.

(Whereupon, Exhibit No. 4 was marked for identification and was received in evidence.)

JUDGE MYATT: Are there any questions of Mr. Mazzocchi?

Apparently there are none, Mr. Mazzocchi.

We will take at this moment a brief recess before we get to Dr. Maltoni.

(Whereupon, a short recess was taken.)

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JUDGE MYATT: The next oral presentation will be given by Prof. Cesare Maltoni of Italy.

While Prof. Maltoni is coming forward, I might announce to you that more copies of the schedule of appearances are being reproduced. Some of you have asked during the recess whether there will be copies. They are being reproduced and they will be available for you.

Prof. Maltoni.

PROF. CESARE MALTONI

PROF. MALTONI: Probably my English is not so good, so I will go as slowly as I can.

The project of investigating the oncogenic potential of vinyl chloride followed the preliminary results of the pioneering work of Prof. Viola presented at the Tenth International Congress which took place in Houston in 1970 and was then extensively published in "Cancer Research" in 1971.

Prof. Viola's results indicated that the exposure to 30,000 ppm of vinyl chloride four hours a day, five times weekly, for ten months produced tumors in rats. These tumors were interpreted by Prof. Viola as arising in skin, lungs, and bones.

Immediately after the report in Houston, we got in touch with Prof. Viola, who kindly put at our disposal the manuscript of his extensive report still being printed and several slides of the tumors.

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On the basis of Prof. Viola's results and material, we reached the following conclusions: under Prof. Viola's experimental conditions, vinyl chloride definitely showed a carcinogenic effect on rats.

2. 30,000 ppm of vinyl chloride was an extremely high level of exposure.

3. The tumors described as cutaneous were arising in the Zymbal glands, which is a sebaceous gland of the ear duct, which in rats are responsive to a large specter of carcinogens, such as acetyl-amino-fluorene, polycyclic hydrocarbons, aminostilbenes, benzidine, ethyl-carbamate, et cetera.

4. The tumors described as lung tumors were most likely metastases from Zymbal gland carcinomas. The pulmonary neoplastic deposits were in fact morphologically similar to the Zymbal gland carcinomas, and all were observed in animals bearing Zymbal gland tumors, which was an important fact since we know that lungs of rats is extremely resistant to develop cancer.

The need, therefore, emerged for an extensive investigation to further clarify the type and degree of carcinogenic effects of vinyl chloride with particular emphasis on experimental factors related to exposure, such as route, concentration, length, which could give more direct indications about the risk and degree of occupational condi-

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tionstitute.

For these purposes, and since in our country our Institute is particularly oriented towards studies on cancer prevention and control, we were contacted by Montedison Society to undertake the experimental project on the biological effects of vinyl chloride. Montedison was soon joined by ICI, Solvay, and Rhone-Pegil.

To start the operative phase of the research, we needed, first of all, to prepare proper conditions for atmospheric exposure. The studying and building of an apparatus for programmed and controlled exposure took us several months. Such an apparatus makes it possible to deliver concentrations varying from 30,000 ppm to 50 ppm and to treat simultaneously 900 experimental rodents twice daily, so, per day, 1,800 animals. Basically it is built of inoxidable steel and glass.

VC has been supplied by Montedison. Each stock has been analyzed before the use in the chemical research laboratory of Montedison itself.

The experiments are mainly performed on Sprague-Dawley rats; Wistar rats, Swiss mice, and hamsters have also been used. All the animals, except for hamsters, have been bred in our Institute for years and, whatever their use, they are all examined at death by complete autopsy, which means that we know their current pathology quite well.

Thirteen experiments have been started in sequence.

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Some of them were programmed at the beginning; for some others the need appeared on the basis of the first experimental results. The plan of the experiments and the up-to-date situation is shown in the following tables.

(At this point, various slides were shown.)

PROF. MALTONI: Experiment 1 studies the effect of the atmospheric exposure to 10,000, 6,000, 2,500, 500, 250, 50 ppm of VC, four hours daily, five days weekly, for twelve months. Two groups of animals were added as control, one untreated, as for all the following experiments, and one treated with vinyl acetate at 2,500 ppm, under the same experimental conditions. This dose of vinyl acetate appeared to be the maximal possible dose for a chronic exposure.

Experiment 2 was performed to investigate in a larger number of animals the effect of doses among 250 and 50, that is, 200, 150, and 100 ppm, under the same conditions as Experiment 1. It started after it was clear that 250 ppm was still showing oncogenic effects on the basis of the first experiment.

In the last column are shown the weeks from the beginning of the experiment.

Experiment 3 was planned to study the effect of a shorter period of exposure, keeping all the other conditions of Experiment 1.

Experiment 4 studies the effect of the same type of

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exposure as Experiment 1 in another species, that is, mice. The treatment lasted seven months in consideration of the higher mortality and shorter lifespan of the mice of the strain used.

Experiment 5 was undertaken as a pilot investigation for the possible effects of the atmospheric exposure during pregnancy on offsprings.

Experiment 6. We wanted to reproduce the same conditions of Prof. Viola's experiment. That means an exposure to 30,000 ppm.

Experiment 7 was planned to study the effect of the same type of exposure as Experiment 1 in another strain of rats, that is, Wister rats.

Experiment 8 studies the effects of the same exposure as Experiment 1, which means four hours daily, five days weekly, for twelve months, in a third species, that is, hamsters, for the same period as Experiment 4.

Experiment 9 was planned to further assess whether or not inhalation of VC had any effect at a dose level of 50 ppm. The first group we treated in Experiment 1 was with 60 animals. This we thought was not a sufficient large number of animals, and, so, recently we started another experiment in which we put under treatment 300 animals treated with 50 ppm of VC daily, for four hours daily, five days weekly, for twelve months.

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the legs and feet, and any other organ with any pathological lesions. All the animals exposed to the highest does, 30,000 and 10,000 ppm, with or without tumors, were examined radiologically during the treatment and/or after the death. Moreover, radiological examinations were made on animals bearing tumors though exposed to the lower doses.

The preliminary results and the other data on the up-to-date situation of the Experiments 1, 3, 5, and 6 are given on the following Tables 2 to 5. For what concerns the other experiments we have still to wait for results, since they started not a long time ago.

This is the first experiment in which I summarize; the rats have been exposed four hours daily, five days weekly, for twelve months, and kept alive until death. The first group is vinyl acetate, 96 animals there treated with 2,500 ppm. No tumor was observed.

In the second group, 10,000 ppm of vinyl chloride, as the other, 69 animals, and we got 13 Zymbal glands carconomas, 3 nephroblastomas, 6 liver angiosarcomas, 5 tumor in other site or type, which I will describe in a moment.

For what concerns 6,000 ppm, we got 5 tumors of Zymbal glands, 3 nephroblastomas, 11 liver angiosarcomas, and 2 tumor other site.

With 2,500 ppm we got 2 Zymbal glands tumors, 6 nephroblastomas, and 9 liver angiosarcomas, and 4 tumor of

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other site.

It seems sort of paradoxical since in this group the number of nephroblastomas are higher than in the other group, but, meanwhile, tumor of the Zymbal glands started quite heavily, tumor of kidney and liver arose after in time.

On 67 animals, 500 ppm, we got 3 Zymbal glands tumors, 3 nephroblastomas, 7 liver angiosarcomas, 3 tumor of other site and/or type.

At the exposure of 250 ppm, we got no Zymbal glands tumors, 5 nephroblastomas, 2 liver angiosarcomas, and 4 tumor other site and/or type.

And, so, the total number of the tumors was 27, 21, 21, 16, 11, and zero in the group with 50 and zero in the group of negative control, so the total number of tumor was 96 over a total number of animals of 577.

I have to say that up to the present moment we have three survivors after 127 weeks from the beginning of treatment in the group of 50, but up to the present moment no tumor appeared in this group.

The tumors are analyzed in the following table, but I prefer to illustrate here the results of these slides. Several of the Zymbal gland carcinomas metastasized to lungs and this was the misinterpretation of lung carcinoma in every experiment.

What concerned nephroblastoma, they metastasized to

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liver, to lung, and to spleen.

For what concerns liver angiosarcomas, these metastasized to lung.

For what concerns the other tumors in other site and of other type, of the five which arose in the second group treated with 10,000 ppm, we observed 2 Zymbal glands adenomas, 1 neurilemmoma of the ear cartilage (inaudible), 1 mammary carcinoma, and 1 cystoadenocarcinoma of ovary.

For what concerns the two tumors which arose in the group treated with 6,000 ppm, we observed 1 angiosarcoma in subcutaneous fibrosing angioma and 1 sebaceous gland carcinoma of the skin.

For what concerns the group treated with 2,500 ppm, we observed 1 Zymbal gland adenoma, 2 intrabdominal angiosarcomas, one next to spleen and one next to ovary, 1 ossifying angiosarcoma of the neck.

For what concerns the group treated with 250 ppm -- no, I beg your pardon. It's 500 ppm -- we got 1 pulmonary angiosarcoma, 1 angiosarcoma of the uterus, 1 minimal deviation hepatoma.

And for what concerns the four tumors in the 250 ppm group, we observed 1 Zymbal gland adenoma, 1 intrabdominal angiosarcoma next to spleen, 1 intrathoracic ossifying angiosarcoma, and 1 salivary gland carcinoma.

They're summarized there, but I already told.

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In this slide is shown the same design experiment, but instead of one year of exposure, here we have four months of exposure, and the animal there kept during all the lifetime and we were continuously controlled. Up to the present moment -- after 56 weeks of experiment with four months of exposure, we observed 3 tumor carcinoma of the Zymbal glands and one carcinoma of the Zymbal gland in the group with 6,000. No nephroblastomas and no angiosarcomas and no tumor in other site.

To have a better comparison of the two experiments, I point out that at 50 weeks after the beginning of treatment when the treatment was performed long throughout one year, we observed at the same distance from the beginning of the experiment 11 Zymbal gland tumors instead of three in the first group, one nephroblastoma, one liver angiosarcoma, and three other tumor in other site or type.

In the second group, we have 3 Zymbal gland tumors, one nephroblastoma, three liver angiosarcoma, and one tumor of other site.

For what concerns the third group, we had two Zymbal gland tumors, one nephroblastoma, one angiosarcoma of liver, and one tumor of other site.

For what concerns 500 ppm, we got one Zymbal gland tumor, one liver angiosarcoma.

And for what concerns 250, we have already gotten

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one liver angiosarcoma.

And so it means in reducing the length of exposure the neoplastic response, as much as we may say at 56 weeks, it dropped in a sensible way.

This is the result of the group in which we reproduced the same condition as the other experiment, and over 60 animals treated with 30,000 ppm, all surviving up to the present moment, no weight decrease, no nothing, and so you may follow quite well the sarcogenic effect. We got two tumors of Zymbal glands after 31 weeks. The first arose 22 weeks after the beginning of treatment.

This is the results of part of the experiment to study the exposure of the mother on the offspring during pregnancy. Of a total of 60 breeders, 30 esposed to 10,000 ppm and 30 exposed to 6,000 ppm, 28 are still surviving after 65 weeks. They were exposed for six days, from the twelfth to eighteenth day of pregnancy. No tumor was observed in the mother, but two tumor were observed in the offspring, one in each group. They were not brothers, the two offsprings. They were not from the same mother. And both have a subcutaneous fibrosing angiosarcoma of the same type we observed in the subcutaneous angiosarcoma as I reported..

Zymbal gland carcinomas, liver angiosarcomas and kidney nephroblastomas have never been observed as occurring spontaneously in our breed of Sprague-Dawley rats.

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And now I would like to show many people acquainted with pathology how they look, these tumors.

This is the type of cage, of cell, we used, and this is inside our laboratory.

This is a tumor -- an animal with a Zymbal gland tumor.

This is still more Zymbal gland tumor, and this is -- sometimes it arise a double type of mass. It's still a Zymbal gland tumor.

This is a (inaudible) Zymbal gland tumor.

This is a small Zymbal gland as it is looking normally. It is a (inaudible) low subaceous gland near the ear duct at the limit of the cartilaginous part with the ossified part.

This is a gland as it is looking in an older animal, with a sort of dilatation of ducts and (inaudible).

This is an ossifying carcinoma of Zymbal gland.

This is a solid less differentiated carcinoma of the Zymbal gland.

This is a fully (anaplastic) carcinoma of the Zymbal gland with a very rich (stroma).

This is a polymorphic Zymbal gland carcinoma, and this is (angiocarcinoma) type of Zymbal gland carcinoma.

This is the same type glandular type, very rich in stroma.

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This is as it appeared, the lung metasteses which were misunderstood primary. One of the characters to judge this primary tumor was the angiosarcoma is very frequent also in Zymbal glands.

These are the (inaudible) magnification. This is a metasteses to lung (inaudible) carcinoma with a rich stroma.

This is as it appear kidney nephroblastoma.

Again another kidney nephroblastoma.

Again another nephroblastoma.

This shows quite clearly the picture, the (inaudible) picture of this tumor in which one may see some embryonic-like aspect of (inaudible).

This is better up here.

This is a liver metasteses of nephroblastoma with this (inaudible) slide picture.

This is a spleen metasteses.

This is a lung metasteses nephroblastoma.

This is a magnification of lung metasteses nephroblastoma.

This is an early angiosarcoma of liver. It appears like these red (blips).

This is, again, in the middle of the lobe an angiosarcoma.

This is a larger liver angiosarcoma.

This is a larger liver angiosarcoma.

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This -- it doesn't appear quite right, but many of these angiosarcoma got excluded from the general circulation and so they undergo some degenerative -- and this is one which looks whitish.

This is an angiosarcoma in (inaudible) liver.

This is how it looks morphologically, very well differentiated angiosarcoma. The effect of the angiosarcoma was seen by us some 14 months and I do believe that it has been one of the first times in literature in which one could predict and orient the following epidemiological investigation.

This is again an angiosarcoma of liver.

This is an angiosarcoma in lung primary.

This is a metastetes in lung angiosarcoma.

Again, metasteses of angiosarcoma to lung.

This is associated, angiosarcoma and a nephroblastoma.

Again an association of early angiosarcoma with a quite large nephroblastoma.

This is the subaceous gland carcinoma of the skin.

This is an ossifying angiosarcoma of neck.

The not ossifying part reproduced by (inaudible).

This is the ossifying part, and this is the lung metasteses of the same tumor.

This is again a primary of lung angiosarcoma.

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This is peritoneal angiosarcoma.

Again, peritoneal (inaudible) angiosarcoma.

Again, another peritoneal angiosarcoma.

This is an ovarian angiosarcoma.

This is an equivalent slide.

This is a uterine angiosarcoma, and this is the corresponding slide.

This a subcutaneous angiosarcoma arising in subcutaneous (inaudible), and you will see very nicely the malignant parts and the benign part.

This is (inaudible).

This is salivary gland carcinoma, and this is the corresponding slide.

Three cases of spontaneously occurring Zymbal gland carcinoma -- as I told, Zymbal gland carcinomas, liver angiosarcomas, and kidney nephroblastomas have never occurred spontaneously in our breed of Sprague-Dawley rats.

Three cases of spontaneously occurring Zymbal gland tumors have been recorded in Sprague-Dawley rats in 1962 by Dr. (Fadiman) in Chicago and myself, and I think they are the only three cases of spontaneously occurring Zymbal gland carcinoma ever described in literature.

To our knowledge, no spontaneous nephroblastomas and liver angiosarcomas of rats have been reported in Italy.

As far as we know, kidney nephroblastomas have

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never been reported to be experimentally induced.

As far as liver angiosarcomas are concerned, they have never been experimentally induced in rats. Liver angiosarcomas of a different morphological type and with a much less malignant picture have been described in mice following long-term treatment with ethel-carbamate.

Liver angiosarcomas are quite rare in man. Few cases -- exactly three cases have been reported in humans following medical exposure to radium and thorotrast.

Now our experiments are in progress and I think that the most important part is this one which deals with the long-term exposure to very low doses. I mean 200 ppm, 150 ppm, 100 ppm, and the larger experiment of 50. To wait for the end of the experiment, four months of exposure, and then also to wait for the results of intermittent high doses experiment. (Inaudible) I do believe we have to be careful to look on the effect on oral administration by gavage of control doses because this has a wider implication than merely occupational aspects.

With the corroboration -- we were asked also by Montedison for corroboration on control of exposed workers and we have now several hundred people under such medical control. This medical control consists mainly of a medical examination, radiological examination, and cytological examination of sputum and urinary sediment.

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As much as concerns sputum, we got probably the most interesting results. We have observed in a small part of workers a sort of (metaplastic) lesion of the respiratory (inaudible) of a morphological type. We have a slide I'm ready to present if anybody is interested on it, that we have never observed on other type of (inaudible).

Thank you.

JUDGE MYATT: Professor, would you remain seated?

We're ready to proceed now, if there are any questions.

Mr. Bien?

MR. BIEN: Could you tell --

JUDGE MYATT: Identify yourself for the record.

MR. BIEN: Ching-Tsen Bien, Occupational Safety and Health.

Could you tell the possible concentration level which has no effect (inaudible).

PROF. MALTONI: I don't know if I get your question exactly, but you ask me if I think --

MR. BIEN: It's possible a concentration level which would not induce any cancer.

PROF. MALTONI: As I told you in my report, we didn't get up to now tumor at 50 ppm level, but the group with which we started was in a way limited because there were only 60 rats, and so we now undertook a much larger

experiment on 300 animals, treated animals, in order to assess in a more definitive way if or not at that dose level in our experimental condition CVM does not produce or does produce tumors.

MR. BIEN: If you can find a level which is safe for the animals, what would the ratio be between this level which would also be safe for human exposure? If you find the concentration at 50 is safe for the animals, what would be the safe level for the human exposure?

PROF. MALTONI: I would say that it is very difficult to -- at such a low dosage to extrapolate at the present moment on rats directly to man. I would say that we are looking now to have further evidence to show that 50 ppm are not carcinogenic for rats, and, so, since the group at starting was too little, we are going now further with this second investigation. We could say that if in this condition we don't get tumor, I think that at that moment we have to start to look how we can extrapolate this data to human situation.

MR. BIEN: On your further study, are you trying to get some primates for your animal experimentation, monkeys, chimpanzees, or not?

PROF. MALTONI: No, no. It is only done on rodents, different types of rodents.

MR. BIEN: Thank you.

DR. KEANE: Dr. Marcus Keane, NIOSH.

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Prof. Maltoni, I'm especially interested in the remarks you made near the end of your presentation recounting the clinical following of exposed workers and finding positive sputum cytology results -- did I understand you correctly?

PROF. MALTONI: No, I worry I didn't make myself clear. We didn't find positive -- to say "positive" would have meant that we find (neoplastic) cell. We did not observe (neoplastic) cell. We observed a kind of metaplasia -- of metaplasia of the respiratory tract epithelium which means to be quite -- I wouldn't say specific, but which we have observed quite rarely in other group of population but which is present in several cases in these exposed people. Metaplasia -- the meaning of metaplasia, (inaudible) metaplasia, it's not so clear in relation to cancer. It doesn't mean the sputum was positive.

I only say we show a kind of change which seemed to be in a way peculiar of this exposure, and if you want to see, I may show to you.

MR. ROSE: Vern Rose from NIOSH.

Did you analyze the purity and/or possible contaminants of the vinyl chloride which you used in the animal experiments that you've described?

PROF. MALTONI: The vinyl chloride, as I told you, it was analyzed in Montedison's experimental unit and their

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impurities were very, very low -- I would not say zero, but near zero.

JUDGE MYATT: Miss Gholston?

MS. GHOLSTON: Could I ask you, are there any regulations in Europe with respect to exposure to vinyl chloride?

PROF. MALTONI: I think that there are rules, and before, it was to keep the exposure below 250 ppm, but I think that recently the recommendation has been adopted, made and adopted to keep as low as possible. Now I think that it's kept below 100 ppm, but orientation is to lower it down under 50.

JUDGE MYATT: Yes, sir?

DR. JAEGER: Dr. Jaeger, Harvard University School of Public Health.

I'm concerned about the purity of vinyl chloride. Although 250 parts per million is a very low level, can you give me any information on the purity, an absolute number -- can you give me any information on possible contaminants, or is there a representative of the laboratory here that can tell us about that?

PROF. MALTONI: I'm sorry, I have not here the (inaudible) of analysis, but I can send you, if you want.

DR. JAEGER: Are you using the same batch throughout your entire study, or is there a variation in the batch?

PROF. MALTONI: I would say that I think that it is always the same type of vinyl chloride, but it could be, I think, of not great value as much as it is analyzed each time.

JUDGE MYATT: Are there any other questions?

I have been informed that the slides will be photographed and made a part of the record, so that they will be available as a part of this record.

Are there any other questions of Prof. Maltoni?

DR. SELIKOFF: Selikoff of Mount Sinai.

No question, but I rise merely to voice the thanks of the American scientific community for the beautiful piece of work you've done.

PROF. MALTONI: Thank you very much.

(Applause.)

JUDGE MYATT: All right, Professor. Thank you.

The Professor's submission will be, for the record, identified as Exhibit 6, and 6(a) will be the photographs of the slides.

(Whereupon, Exhibit No. 6 was marked for identification and was received in evidence.)

JUDGE MYATT: It is my intention, since we have such a large number who are listed to appear here, to go until approximately 12:30 before we adjourn for lunch.

Accordingly, I'm going to ask Mr. A. C. Clark for the Manufacturing Chemists Association to come forward with

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his presentation.

ALBERT C. CLARK

MR. CLARK: My name is Albert C. Clark. I'm Vice-President and Technical Director of the Manufacturing Chemists Association.

With me here today is Dr. Kenneth E. Johnson, Assistant Technical Director of MCA.

Before beginning my formal presentation, I would just like to comment -- make reference to a comment by Mr. Rose regarding the suggested work practices. Shortly after receiving the communication from Dr. Key, I think you'll be interested to learn that copies of the work practices were distributed to the medical contacts of all MCA member companies, as well as to members of several of the concerned functional committees.

The Manufacturing Chemists Association is a non-profit trade association have 174 United States member companies representing more than 90 percent of the production capacity of basic industrial chemicals within this country.

With respect to vinyl chloride, the subject of this hearing, over 97 percent of the production capacity reported by Chemical and Engineering News in May 1973 was in our members' plants. For the polymer plants, the corresponding figure was then nearly 88 percent.

Vinyl chloride is a chemical derived ultimately

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from petrochemical feedstocks and chlorine. Of the 5.2 billion pounds of the monomer produced by U. S. Industry in 1972, all but a small fraction -- less than one percent -- was used in the production of various plastics -- primarily plyvinyl chloride, but including a wide variety of co-polymers with other monomers. Among the plastics, only the production of polyethylene exceeds that if PVC.

The importance of PVC production is not measured just by the value of the unprocessed polymer, but more properly by the almost universal dependence of nearly every branch of industrial and commercial activity upon products and components fabricated from this plastic.

With this statement, we are submitting a description of the industry and its products that appeared in the December 1973 issue of Plastics Engineering, and we ask that this reprint be made a portion of the record of this hearing. This report makes it clear that the VC/PVC industry involves a wide variety of chemicals -- initiators, catalysts, plasticizers, stabilizers, antistatic agents, fillers, pigments, and a host of other specialized, but generally very minor, additives. Under such circumstances, the identification of any adverse health effects among the employees of a vertically-integrated VC/PVC plant with a specific causative agent becomes complex.

A few more statistics concerning the industry may

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be helpful. The U. S. VC/PVC industry has been operating over forty years and over the past five years has shown an annually compounded growth rate of 14 percent -- a rate of growth that is expected to taper off only modestly in the next few years to about 11 percent. U. S. production now represents about one-fourth of the world total.

Synthesis of the monomer is conducted in fourteen U. S. plants, and 37 plants are engaged in polymerization. It is estimated that about 1,500 workers are employed in monomer synthesis, and an additional 5,000 in polymerization operations.

It is difficult to estimate the number of workers employed in converting, molding, and fabricating these polymers, but they are numbered in tens of thousands, working in thousands of plants. It has been estimated the wholesale value of the annual output of fabricated products is over $3 billion.

MCA, as a regular and continuing service to its members, has long had active programs in occupational health and safety. Its past and current activities with respect to vinyl chloride are a natural outgrowth of these programs. MCA's Safety and Fire Protection Committee is now in its twenty-eigth year. Among its other activities, it has prepared MCA's highly respected series of Chemical Safety Data Sheets for commodity chemicals throughout this period. One on

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vinyl chloride -- SD-56 -- was first issued in 1954 and last revised in 1972..

A Medical Advisory Committee was formed in 1946, later reconstituted with the addition of industrial hygiene engineers, toxicologists, statisticians, and other specialists in employee health, and renamed the Occupational Health Committee.

Additionally, MCA is prepared to administer special programs on behalf of groups of interested companies in instances where only a limited number are directly involved.

Thus, in 1966 when companies were alerted by the European reports of an occupational disease among PVC polymerization kettle cleaners, a project was established at the University of Michigan's School of Public Health to determine the nature, extent, and etiology of the condition known as occupational acroosteolysis. The results of this study have been published by Drs. Harold J. Magnuson, Bertram D. Dinman, and others in a series of three papers in the Archives of Environmental Health, January 1971. Although the role, if any, of vinyl chloride in the causation of this condition could not be defined, the industrial hygiene controls and improved work practices adopted by the industry have led to a decline to almost zero in the number of new cases of even very mild forms of this disease.

It was in an effort to develop an animal model of

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this condition that the first observations of possible carcinogenesis by vinyl chloride were made. Dr. P. L. Viola, in a report published in March 1970, reported that rats exposed to 30,000 ppm vinyl chloride vapors for four hours per day, five days per week for a year, showed "degeneration of the skeleton and connective tissue with histopathological pictures similar to those observed in human acroosteolysis of the hands." In his paper, no mention is made of the appearance of any malignant tumors.

A few months later, however, at the Tenth International Cancer Congress, Dr. Viola briefly described observations of malignant tumors in the ear canals of rats subjected to an exposure protocol almost identical with that in his earlier paper. He also reported tumors in the lungs and bones of these rats, but closed his abstract with the specific disclaimer: "No implications to human pathology can be extrapolated from the experimental model reported in this paper."

MCA invited Dr. Viola to come to the United States as a guest of the industry for a discussion with U. S. occupational health experts. On May 5 and 6, 1971, at a meeting with MCA's Occupational Health Committee he discussed his more detailed report then in press and referred to other studies completed or underway. Dr. Viola spoke of these unreported studies only in rather general terms and declined to

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reveal details. He acknowledged that his vinyl chloride was of low purity, but expressed his personal opinion that it was the vinyl chloride per se and not any impurities that was responsible for the pathology he was observing. He claimed to have seen tumors in rats exposed to 5,000 ppm, but expected the results would be negative at half that level. In his opinion the 500 ppm TLV provided an adequate margin of safety of employees from the tumor induction he had seen in rats at the higher levels. We are not aware of any further publications by Dr. Viola on this subject.

The disparity between Dr. Viola's findings and the relatively low toxicity reported by earlier researchers was immediately recognized. For many years vinyl chloride monomer was considered to be very low in toxicity, but from single and repeated exposure. Because of its volatility, inhalation was considered the only important route of exposure for workmen. The high flammability of VCM has been considered to be a more serious hazard than inhalation.

From the earliest lists until 1962 the American Conference of Governmental Industrial Hygienists, ACGIH, recommended that the time-weighted average, long-term, seven- to eight-hour daily exposure of workmen to vinyl chloride not exceed 500 ppm. This recommendation was based on single exposure studies on animals and on human experience. Recommended time-weighted average concentrations are published by

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ACGIH in an annual list of "Threshold Limit Values." A TLV was considered by this group to "represent conditions under which it is believed that nearly all workers may be repeatedly exposed, day after day, without adverse effect."

In 1963 the ACGIH modified their recommendation so that 500 ppm was to be a maximum concentration, or ceiling, rather than a time-weighted average. It is this standard that is in the 1970 TLV list promulgated by OSHA on May 29, 1971, as a national consensus standard.

The change from a time-weighted to a ceiling standard was, in part, due to the publication by Torkelson, Oyen, and Rowe of the results of six-month repeated inhalation studies on laboratory animals. These authors reported slight reversible liver injury in rats exposed even hours per day to 100 ppm, and recommended that the time-weighted average exposure of workers not exceed 50 ppm. This recommendation was not deemed appropriate by Lester, Greenberg, and Adams, however, who did not consider significant injury to have resulted in rats which they had repeatedly exposed to 500 ppm.

In 1970 the ACGIH proposed reduction of their recommended TLV to a time-weighted average of 200 ppm primarily on the basis of work reported by Kramer and Mutchler. The authors reported evidence of clinical findings in workers exposed to time-weighted average concentrations of 300 ppm

[illegible] chloride for two



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vinyl chloride for many years.

In 1972 the ACGIH took vinyl chloride from the list of Intended Changes and revised the value in their regular list to 200 ppm. This value remains the recommended value in the 1973 list. A copy of the documentation for the ACGIH TLV for vinyl chloride is provided as an attachment to this statement.

In view of these developments, it was recommended that MCA convene a conference of vinyl chloride manufacturers to discuss the prospect and feasibility of establishing an industry-supported research program. This meeting, attended by representatives of U. S., Canadian, and European firms, took place on November 16, 1971. On the initiative of companies attending, a research project was formed with MCA participating in an administrative role.

Subsequently we learned of further work being conducted in Europe and, fortunately, were able to establish and maintain liaison.

A contract with the Industrial BIO-TEST Laboratories, Inc., of Northbrook, Illinois, was signed on February 1, 1973. The complete experimental protocol is submitted as an attachment to this statement. The specific goals in mind were:

To attempt to duplicate the European observations with vinyl chloride of a source and quality characteristic of the U. S. Industrial product;

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To extend these studies to two other species of laboratory rodents, mice and hamsters, to determine whether the response of rats might be species-specific;

To develop dose-response relationships with higher limits of statistical confidence to permit estimation of potential risks at occupational levels of exposure with greater precision; and,

To determine what the no-response level is.

In these studies on rats, mice, and hamsters, groups of 100 male and 100 female of each [illegible]s, 600 animals at each exposure level, are being exp[illegible] to either zero, control, 2,500 ppm, 200 ppm or 50 ppm of vinyl chloride monomer, seven hours per day, five days per week, for twelve months. They will then be observed for an additional twelve months, six months for the mice. These animals will not have food and water during exposure.

This "lifetime" study is designed primarily as a cancer study and will include only a limited amount of other observations. Because Viola's studies involved simultaneous exposure of food, water, and bedding, a separate group of 100 rats of one sex is being exposed to 2,500 ppm along with their food, water, and bedding. This has been included because of the possibility that a reaction of the vinyl chloride monomer with either the food, water or bedding may result in a toxic reaction product.

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Although animal exposures started in July 1973, equipment problems gave rise to a number of uncertainties that might have compromised the validity of the results, hence the initial group of animals was discarded and a new set procured. The new exposures got underway on September 10, 1973.

Up to this time, no significant results have been observed in this study, nor would the appearance of any tumors be expected in so short a time. We will keep both OSHA and NIOSH informed as this study progresses.

Recognizing that there must always exist a substantial degree of uncertainty in extrapolating the results of animal studies to the evaluation of workplace hazards, MCA has contracted with Tabershaw-Cooper Associates of Berkeley, California, to conduct a study of the causes of death in vinyl chloride and polyvinyl chloride production workers. The objectives are:

1. To compare the mortality of individuals who have worked in vinyl chloride plants with that of the general population, corrected for age, area, and sex.

2. To compare mortality patterns within the population of vinyl chloride workers, based upon estimated occupational exposure; and,

3. To compare mortality among vinyl chloride workers with the mortality of other occupational groups which TCA

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has studied.

This study is now in its eighth month, and a final report is expected to be issued in April. A copy of the protocol is submitted with this statement.

Although the mortality statistics are as yet incomplete, and have not been analyzed, a preliminary review of the current data from all plants, other than the one concerning which the B. F. Goodrich Chemical Company has made a public disclosure, fails to show any obvious departure from the pattern and incidence of the deaths that would be expected among a population of the kind that has been the subject of this survey.

We will, of course, provide OSHA and NIOSH with the final report and alert them promptly should any significant evidence of occupationally-related deaths appear earlier.

MCA's first direct contact with NIOSH specifically on vinyl chloride led to a conference between an industry delegation, including a European representative, and Dr. Marcus Key and staff on July 17, 1973, at which time the MCA program was presented in some detail, and study protocols, industry statistics, and selected items from the scientific literature were provided.

Under these circumstances, the VC producing and consuming companies participating in the MCA-administered program were understandably greatly concerned when informed on

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January 22 by the B. F. Goodrich Chemical Company of the events that have led to the hearing now in progress. A meeting of the representatives of these companies was held on January 25 under MCA auspices to receive a comprehensive report from Goodrich and to plan and implement any necessary steps not only for the protection of their workers, but also to hasten the resolution of remaining uncertainties.

MCA then immediately contacted NIOSH and, both by telephone and by confirming letter, gave assurance of full cooperation and support in their investigation and development of recommendations for the control of hazards from this source.

MCA publicly announced that it is temporarily withdrawing its Chemical Safety Data Sheet for vinyl chloride, which recognized Dr. Viola's work, but stated that "...many years of industrial experience with human exposures to concentrations frequently far above current standards have not demonstrated any carcinogenicity to humans." MCA will expedite the reissue of this data sheet, revised as necessary to reflect new knowledge concerning possible hazards of vinyl chloride exposures. A copy of a February 6, 1974, news release on the withdrawal is attached.

As discussed herein, manufacturers are aware of the potential hazard of vinyl chloride and, we are informed, are voluntarily taking steps to reduce employee exposure.

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Substantial research is now in progress, the results of which they believe will provide a firm basis for any standard applicable to vinyl chloride-polyvinyl chloride manufacture. Therefore, it is their recommendation that OSHA proceed under the provisions of Section 6(b) of the Act.

On behalf of its producer members, MCA pledges full cooperation with both NIOSH and OSHA as they attempt to define the hazards now tentatively identified with vinyl chloride, and develop standards that will assure the safety of workers in this industry.

Thank you.

JUDGE MYATT: MCA's submission will be Exhibit No. 7.

(Whereupon, Exhibit No. 7 was marked for identification and was received in evidence.)

JUDGE MYATT: Are there any questions of Mr. Clark?

MS. GHOLSTON: Mr. Clark, you said that so far you didn't think that there were adverse health effects that could be attributed to vinyl chloride because of all the different additives that were also involved in the production of vinyl chloride and PVC.

MR. CLARK: Maybe I didn't quite understand you.

MS. GHOLSTON: You said that you did not think you could say outright that there were adverse health effects attributable to vinyl chloride because there were many other additives that could also possibly cause cancer.

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MR. CLARK: Oh. I don't think I said that. I said it was difficult to be specific regarding vinyl chloride.

MS. GHOLSTON: Now, with respect to the other additives, has any effort been made by MCA or any of its members to find out if any of the other additives are carcinogenic?

MR. CLARK: No.

MS. GHOLSTON: The vinyl chloride data sheet that you mentioned earlier, you said it's been withdrawn?

MR. CLARK: Yes.

MS. GHOLSTON: Is this to revise it?

MR. CLARK: Correct.

MS. GHOLSTON: In light of the carcinogenic possibilities?

MR. CLARK: In light of recent developments, that's correct.

I might add that the other recommendations regarding work practices, we still feel is very valid.

MS. GHOLSTON: You also mentioned that you instituted some work practices that led to a decline in the cases -- I think that's what you said -- of cancer. Am I right?

MR. CLARK: Acroosteolysis.

MS. GHOLSTON: How many cases of this, do you know, were there discovered among the member companies?

DR. JOHNSON: I don't have that information with me

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at the present time.

Were the reprints included in the enclosures, Mr. Clark?

MR. CLARK: I don't think so.

DR. JOHNSON: I'll be glad to supply you with a full set of the reprints of the articles by Dr. Magnuson, et al., which is a very comprehensive study.

MS. GHOLSTON: Can you tell me -- you mentioned 500 ppm. Now, do you consider that a safe level of exposure for workers, or would you suggest another level?

MR. CLARK: I'm not prepared to comment on any of that at this time.

MS. GHOLSTON: Can I ask you, you mentioned that you're going to use rodents the same as was used in the older study. Could I ask you, why are you using rodents and not necessarily using primates or other animals?

DR. JOHNSON: It's basically a problem of animal handling difficulties and the expense and space required to get a statistically significant number of the higher species. It requires lifetime exposures to get these cancer studies on a meaningful basis, and the lifetime exposure of a twenty- or thirty-year-old dog or chimpanzee or other higher species gets to be prohibitively expensive and it takes you too long to get answers.

MS. GHOLSTON: Do you think that the rodent body

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and organs are significantly similar to the same organs in the human?

DR. JOHNSON: There certainly are differences. However, the great bulk of experience in carcinogenisists' research has been with the laboratory rodent and, therefore, it is far more convenient for the workers to interpret those results and compare the results they're getting with other studies by staying in these well-studied groups of animals.

MR. GHOLSTON: Specifically, could I ask you if the liver of the rodent is similar to the human?

DR. JOHNSON: Yes, there is a very high degree of similarity, and I believe Dr. Maltoni was discussing earlier the tumors that he found in these rats in his studies were histologically identical with those found in the human cases.

MS. GHOLSTON: Thank you.

JUDGE MYATT: Prof. Jaeger?

DR. JAEGER: May I ask, you stated that you were not conducting studies of other contaminants found in vinyl chloride; you were not assessing their carcinogenesis?

MR. CLARK: That's correct.

DR. JAEGER: But one common constituent of the manufacturing process in vinylidene chloride, a compound that does not currently have a TVL standard, and I believe it was stated on Tuesday that two of the individuals who developed cancer had worked in a vinylidene chloride-vinyl chloride

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process prior to their illness and death. Is there any intention of the industry to study other reactive monomer compounds which may produce cancer in rodents before we find that they produce cancer in man?

MR. CLARK: We have not had, up to this time, any intention to proceed along those lines. What will transpire as a result of the recent discoveries in this incident, I'm not sure.

JUDGE MYATT: Yes, sir?

MR. MAZZOCCHI: Tony Mazzocchi of the Oil, Chemical and Atomic Workers.

Was the MCA aware before today of the documents mentioned in Dr. Selikoff's testimony, the Russian documents and the German documents, and, if so, did they distribute the information from those documents to their members?

MR. CLARK: No, I was not aware of them.

JUDGE MYATT: Are there any further questions?

Let me ask you this: you mentioned that you wanted a copy -- or the reprint made a portion of this record; is that correct?

MR. CLARK: Yes, sir.

JUDGE MYATT: And you're going to supply us with a copy of that, or is it included in the submission?

MR. CLARK: There are nine attachments to my statement, sir, including that.

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JUDGE MYATT: All right.

There being no other questions, thank you, Mr. Clark.

I have twenty-two minutes after 12:00. We're going to take our luncheon break and resume at 2 o'clock with the B. F. Goodrich presentation.

(Whereupon, at 12:22 p. m., the hearing was recessed until 2:00 p. m. of the same day.)

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AFTERNOON SESSION

JUDGE MYATT: The hearing will be resumed.

We have a few more changes. Mr. Donald Holman, the Industrial Hygienist for Control Data Corporation, you can indicate on your list that he will not be making an oral presentation. He has submitted to us a copy of some data he was going to present, and we're going to mark that as Exhibit 8, Madam Reporter.

(Whereupon, Exhibit No. 8 was marked for identification and was received in evidence.)

JUDGE MYATT: That will be in lieu of Mr. Holman's oral presentation.

We also have an additional group to add to the list. Mrs. Andrea Hricko -- how do you pronounce that, madam?

MS. HRICKO: Hricko.

JUDGE MYATT: And Bertram Cottine, representing the Health Research group.

You will list their names as having entered an appearance and, thus, entitled to examine witnesses, although I understand their submission will not be an oral submission but will be a written submission that will be included in the record.

Are the Goodrich people ready? Let's proceed.

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ANTON VITTONE, JR.

MR. VITTONE: My name is Anton Vittone. I am President of B. F. Goodrich Chemical Company, a division of the B. F. Goodrich Company. Our headquarters are 6100 Oak Tree Boulevard, Cleveland, Ohio.

I have prepared a statement from which I will now read and submit for the record of this hearing.

With me to assist in answering questions which may follow this presentation are Maurice N. Johnson, M. D., Director of Environmental Health; Dr. Roger W. Strassburg, Director of Environmental Affairs, and L. B. Crider, Senior Scientist and Specialist in Analytical Chemistry and Monitoring Systems, all of B. F. Goodrich. Their biographies are attached to our written paper.

Over the years our company has sought to maintain a safe working environment through two basic means, containment of potentially or known toxic materials during the manufacturing process and, secondly, protection of our employees through work practices, education, and equipment.

Our efforts to maintain a safe working environment have been in keeping with then known scientific information or data relating to levels of exposure which has resulted in decreasing levels of exposure with time.

Our recent discovery of four deaths from a rare type of liver cancer among employees at our Louisville plant

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was, to our knowledge, the first evidence indicating a possible relationship between human angiosarcoma and chlorinated hydrocarbons used in the production of polyvinyl chloride resins. Our confirmation of the significance of this evidence convinced us that we should report it to our employees and to the federal and state agencies with primary scientific responsibility for occupational health.

Our statement today today will focus on what we have learned about the four deaths at the Louisville plant and our knowledge of previous toxicological data. We will also summarize our program to further safeguard employees now on the job through increased containment of vinyl chloride in processing and reduced worker exposure during all phases of the operation.

The B. F. Goodrich Company began commercial production of polyvinyl chloride resins and compounds in 1937. We currently operate five such plants, at Louisville, Kentucky; Avon Lake, Ohio; Long Beach, California; Henry, Illinois, and Pedricktown, New Jersey, and a vinyl chloride monomer plant at Calvert City, Kentucky. Approximately 1,700 of our employees are engaged directly in these processes. The Louisville, Kentucky, plant is the oldest of our operating polyvinyl chloride resin plants, having initially started production in 1942. We supply finished resins and compounds to about 2,200 domestic customer plants.

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The technologies involved in the production and use of vinyl chloride. There are two types of vinyl chloride monomer processes, acetylene-based and ethylene-based.

B. F. Goodrich has operated both types. Prior to the early 1960's, our principal process of vinyl chloride involved the reaction of acetylene and hydrogen chloride using a Mercuric chloride catalyst deposited on carbon. Starting with a pilot plant at Louisville in 1957 and culminating in a petrochemical complex at Calvert City in 1964, we converted to our present ethylene-based vinyl chloride process.

This consists of three operations: First, reaction of ethylene with chlorine to produce ethylene dichloride; second, thermal cracking of ethylene dichloride to produce vinyl chloride and hydrogen chloride, and, third, reaction of hydrogen chloride with more ethylene in the presence of oxygen to produce more ethylene dichloride. The latter process is known as oxychlorination.

Significantly, the vinyl chloride monomer produced in both processes is distilled to yield commercial vinyl chloride with 99.9 percent purity. The purified vinyl chloride is either pipelined as a liquid under pressure to an adjacent consuming plant or transferred to pressurized tank cars for shipment to other polyvinyl chloride resin plants.

There are four types of polyvinyl chloride

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processes: suspension, emulsion, mass, and solution. B. F. Goodrich Chemical uses the first three types with over three quarters of its production being by the suspension process.

The steps in the process for suspension are: vinyl chloride monomer is received at the plant in pressurized tank cars as a liquid; it is transferred to storage tanks and then piped in a closed system to reactors; water, suspending agents, and catalysts are added to the reactors; polymerization is conducted at controlled temperatures; unreacted monomer is recovered and recycled to the process; water is centrifuged from the stripped polymer slurry and the wet polymer cake is dried; dried polymer is bagged or siloed for bulk shipment or transferred to compound operations.

The emulsion PVC process differs only in the types of emulsifiers and catalysts used in the reactor. Most emulsion PVC processes in our plants are followed by spray drying of the emulsion.

The mass PVC process differs primarily in that it is anhydrous -- no water is used in the polymerization. After unreacted monomer is recovered, the dry powder is packaged.

Compounding. In all of our PVC production plants we convert part of our resins into compounds in powder or cubed form. This compounding operation is the next step towards the finished products. PVC powder is mixed with

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stabilizers, lubricants, and, in some cases, plasticizers in powder mixers of various types. The powder mix is fluxed in internal mixers and subsequently diced or pelletized before packaging for shipment.

B. F. Goodrich toxicity experience. In connection with these processes, our company has had some experiences that we want to review with you in order to complete your understanding of certain factors that promoted us to interpret the most recent events as we did.

In mid-1964, Dr. John L. Creech, our Louisville plant physician, reported that an unusual hand problem had developed among a few employees who entered the polymerization reactors to manually remove the build-up of solid PVC from the reactor walls. This was the first time we encountered a problem anything like this. Dr. Creech's observation was found to confirm European published reports of a similar problem.

We called a meeting with other PVC manufacturers to review the situation and participate with them in an extensive research program through the Manufacturing Chemists Association. We then cooperated in a worldwide investigation of what came to be known as the "hand problem" or acro-osteolysis. Our employees were advised of the problem and a continuing monitoring system of hand x-rays was established at all our plants. These studies of the hand problem

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correlated only with manual cleaning of PVC reactors.

Despite the lack of conclusive evidence as a chemical cause of the hand problem, we initiated an aggressive program to reduce this type of exposure. Goodrich developed a hydraulic reactor cleaning process which is used on all our reactors. The use of hydraulic reactor cleaning reduced substantially the number of entries into reactors and, thus, the manual hand effort, as well as the exposure to vinyl chloride. In the past several years we have observed no new cases of the hand problem.

In May 1970, Dr. P. L. Viola of Rome reported the appearance of tumors in rats exposed to 30,000 parts per million of vinyl chloride vapor in inhalation studies. This level is close to the lower explosive limit of vinyl chloride vapor.

Nevertheless, knowledge of this published information caused the MCA Vinyl Chloride Task Force to initiate a suitable protocol to determine whether tumors could be induced at levels of exposure above or below the 500 parts per million maximum standard then in effect.

In conjunction with the development of this protocol, the MCA task force learned of similar animal research which had been initiated by some European PVC manufacturers some time after Dr. Viola's report.

The MCA animal test program began in September

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1973. In addition, the MCA program was expanded to include an industry-wide epidemiology study now underway.

In January 1973 we intensified air sampling analysis in all our plants to determine more accurately the levels of vinyl chloride monomer exposure. We soon learned that commonly used air sampling techniques were inadequate for fast measurements at low levels for extended periods of time and for determining the cause of any increase in level. Therefore, we investigated all other monitoring techniques, including those being used in other companies, and decided that we needed to develop our own advanced system which would be capable of monitoring at very low levels and over extended periods of time.

While we had been concentrating on reduction of any process loss of vinyl chloride for years, we began a series of special plant manager meetings in mid-1973 to minimize worker exposure to vinyl chloride, to discuss new monitoring systems, and to put into effect new work practices. We established an interim goal of 50 parts per million maximum exposure and are working toward lower levels.

The Louisville situation. In the spring of 1973 Dr. Creech believed that he was observing among some employees an increasing incidence of symptoms normally associated with possible liver ailments. He discussed his concern with Phillip H. Lawrence, manager of the Louisville

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plant, and recommended that liver function tests be initiated among certain groups of the plant's PVC employees.

The company's newly appointed Director of Environmental Health, Dr. Maurice N. Johnson, who is with me today, subsequently went to Louisville and started the testing program involving 271 employees.

The tests which were completed in early December 1973 showed that 55 employees had some evidence of slight liver abnormalities. Because of the known limitations of liver tests, these results were not in themselves a major cause for concern.

On December 18, Dr. Johnson again visited the Louisville plant. He consulted with Dr. Creech on these results and they agreed to retest those employees showing any indication of abnormality. These tests have just been completed and are now being evaluated.

In this meeting Dr. Johnson was informed by Dr. Creech that he had recently learned that an employee died in March 1973 of angiosarcoma of the liver. Dr. Creech also reported that this rare type of cancer prompted him to review medical records concerning another employee and former patient who died of liver cancer in 1971, and that review confirmed it was an angiosarcoma of the liver.

Because of Dr. Creech's growing concern and Dr. Johnson's awareness of other pertinent toxicological studies,

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they reviewed available medical records in the plant and found that another employee had died of an unknown type of liver cancer in 1968. They also learned that another employee was critically ill with a diagnosis of cirrhosis. This man died the following day.

Dr. Johnson returned immediately to Akron for a special meeting with top corporate officers at which the developments at Louisville were reviewed. The decision was made to begin an in-depth investigation with the assistance of outstanding consultants in the field of industrial medicine. Dr. Johnson contacted Tabershaw-Cooper Associates, Inc., of Berkeley, California, because of their reputation and also their involvement in the MCA work that was mentioned earlier. Dr. Johnson met with Dr. Irving R. Tabershaw in California on January 14th and 15th to review all the information then known to the company. Before returning to Akron, Dr. Johnson learned that the cause of the third death which had occurred on December 19th was angiosarcoma of the liver.

Another in a series of top management meetings was held on January 18th to discuss these developments. Dr. Tabershaw flew to Akron for a meeting with corporate and divisional officers on Sunday evening, January 20th.

Because of the possibility that these deaths from a rare type of liver cancer might be work-related, the decision was made to inform the Occupational Safety and

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Health Administration, OSHA, through the Kentucky Department of Labor and the National Institute of Occupational Safety and Health, NIOSH, as well as to provide the essential information to our PVC employees, union officials, and the public.

The initial meeting with NIOSH took place in Washington on January 22nd after Drs. Johnson and Tabershaw returned from a visit to the plant and consultation with Dr. Creech in Louisville on January 21. The notification to OSHA through the Kentucky Department of Labor was made in Louisville by Drs. Johnson and Tabershaw on January 23rd. A public statement was also released by the company on January 23rd. A second statement was issued to the news media on January 29th immediately after it was learned that a review of autopsy records confirmed the cause of the 1968 death as angiosarcoma of the liver.

During this period, Harry B. Warner, President of B. F. Goodrich, Thomas B. Nantz, Executive Vice-President, and I held private meetings with the families of three of the deceased employees. On the same day, Messrs. Warner, Nantz, and I inspected the Louisville plant to observe current work practices and exposure levels. After these observations and consultation with Drs. Johnson and Tabershaw, we concluded that the existing situation warranted continued operation of the polyvinyl chloride facility.

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Epidemiological studies. We have actively supported and participated in both animal and epidemiological studies through the MCA's Vinyl Chloride Task Group of its Occupational Health Committee.

Because of recent developments, we have expanded the scope of our part of the MCA epidemiology study in order to obtain as in-depth a study as possible of employees exposed to vinyl chloride and related chemicals.

The deceased employees had an average exposure of approximately 19 years to vinyl chloride and ten years to vinylidene chloride. They also had variable exposure times to such volatile organic chemicals as vinyl acetate, methyl acrylate, ethyl acrylate, methanol, and chlorinated solvents.

It would be premature to report on the liver activity tests now in process at all our PVC plants or to provide any statistical analysis of the correlation with chemical exposures. We can tell you that no other cases of angiosarcoma have been found in our preliminary review of death records of employees and retirees from Louisville and our other plants. This review is continuing.

Summary. We have attempted to provide information with respect to our findings of four cases of angiosarcoma of the liver of deceased employees of our Louisville, Kentucky, plant which have brought about this hearing. With respect to Item 6 of the agenda, that is, "whether the avail-

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able information warrants the issuance of an Emergency Temporary Standard or the commencement of a regular rule-making under Section 6(b) of the Occupational Safety and Health Act," we recommend that your agency proceed with the regular rule-making procedure under Section 6(b).

We will do all we can to protect the health and safety of our employees. To help achieve these ends, we have brought exposure levels in all our operations below 50 parts per million on a time-weighted average and are working towards lower levels of exposure. Our plant monitoring procedures are reliable and are being improved. We are in the process of providing liver function tests to all exposed employees. We are implementing most of the temporary precautionary procedures recommended by NIOSH on January 31 at all plants as rapidly as possible. Several recommendations will require further clarification and discussion with NIOSH before implementation. Our medical department is working closely with government and other medical authorities to specify the best possible medical screening and testing procedures.

In summary, the clinical evidence associated with the deaths of four of our employees identifies the need for scientific inquiry beyond the experience of any one company or industry group.

Thank you.

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JUDGE MYATT: Thank you, Mr. Vittone.

Your submission will be admitted into the record as Exhibit 9.

(Whereupon, Exhibit No. 9 was marked for identification and was received in evidence.)

JUDGE MYATT: Are there any questions at this point of the Goodrich representatives?

MR. MAZZOCCHI: Tony Mazzocchi, Oil, Chemical, and Atomic Workers.

I heard reference to a search in the European literature after a relationship had developed between bone disease and PVC exposure. My question is: did the searchers of European literature discover the papers referred to by Dr. Selikoff this morning showing the relationship between liver cancer and PVC and VC?

MR. VITTONE: Do you understand the question?

DR. JOHNSON: You mean at the time the research was done on the acroosteolysis cases? I'm not sure, but they are not in the file, so I presume they did not uncover them.

MR. MAZZOCCHI: Does B. F. Goodrich have a European chemical operation?

MR. VITTONE: Yes, we have a European chemical operation. It's not in the manufacture of polyvinyl chloride. We own part of (Ciago), which does make some

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vinyl (inaudible).

MR. MAZZOCCHI: Do they have a corporate medical department?

MR. VITTONE: I don't understand the question.

MR. MAZZOCCHI: Does the European affiliate have a medical department with an M.D.?

MR. VITTONE: The European facility has medical service through our associates there, HAU, currently KZO.

MR. MAZZOCCHI: What country is that in?

MR. VITTONE: It's in Holland.

MR. MAZZOCCHI: I understand there's a Dutch paper also as to the relation between liver disease and vinyl chloride. Your European medical directors would not communicate with your American company when they discover something that might affect the American operation?

MR. VITTONE: We've been trying throughout these many years to keep abreast of any developments in Europe with respect to this area and we will continue to do so.

MR. MAZZOCCHI: Could you describe for us where monitoring is done in the PVC operation? Is it continuous and how is it performed?

MR. VITTONE: Where what is done?

MR. MAZZOCCHI: Monitoring.

MR. VITTONE: We have two systems we're monitoring currently. We're trying to go to a continuous system. We

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have one such installation at Avon Lake and equipment ordered for all of our plants.

The other system is a spot system where we're employing people constantly checking, spot checking, throughout all floors of the buildings.

MR. MAZZOCCHI: I still have two more questions. Are employees told to monitor the readings at the time they're taken?

MR. VITTONE: They see the readings.

MR. MAZZOCCHI: They see the readings?

MR. VITTONE: That is, the employee who takes them sees the readings. They're available on a chart.

MR. MAZZOCCHI: I understand the daughter of an employee at Louisville, an eight-year-old female, has come down with a liver tumor. Can you tell us something about that, whether that is, in fact, true and, if true, what is the diagnosis of that young girl and also where did her father work in the plant?

MR. VITTONE: Do medical ethics allow you to speak on this subject, Dr. Johnson?

DR. JOHNSON: Yes. I think I can be a bit careful, but there was a child of an employee who was reported to have liver cancer and that has been checked out -- by Dr. (Popper), as a matter of fact -- and it was a liver tumor type other than an angiosarcoma, and I don't know what type

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it was. It was not angiosarcoma.

MR. MAZZOCCHI: Can you tell me where her father worked in the plant?

DR. JOHNSON: I don't know.

JUDGE MYATT: Yes, ma'am?

MS. HRICKO: Andrea Hricko, Health Research Group. Can you submit for the record the exact dates, the month and the year, of the deaths of the former employees?

DR. JOHNSON: Chronologically, 1/7/68, 9/27/71, 3/3/73, and 12/19/73.

MS. HRICKO: And what was the date on which Dr. Creech first found that March '73 case? You mentioned --

MR. VITTONE: The March '73, he reported it to Dr. Johnson, I believe, on December 18th.

MS. HRICKO: That was the first notice you had?

MR. VITTONE: That was the first notice to us. You see, that was not a patient of Dr. Creech's.

MS. HRICKO: The other question I have is in regard to the screening tests you're performing on employees. Can you submit a protocol for those liver function tests for the record?

DR. JOHNSON: At the moment we're doing the standard SMA-12, which includes four things that I think one would call fairly directly related, bilirubin, (inaudible), LDH, and STOT, and, I suppose, some of the other more remote--

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MS. HRICKO: I have one more question. Were any of these employees who died of angiosarcoma of the liver retired employees of B. F. Goodrich?

MR. VITTONE: Not to my knowledge.

MS. HRICKO: Does B. F. Goodrich keep track of their retired employees?

MR. VITTONE: Yes, and that's now we have checked the preliminary report that we have made that we have found none other than the four cases. We're checking the records.

MS. HRICKO: Thank you.

JUDGE MYATT: Miss Gholston?

MS. GHOLSTON: Mr. Vittone, have you done anything to determine where the four employees that died from liver cancer worked with respect to the plant? I mean, did they all work in a common point at one point in time?

MR. VITTONE: Yes, we have checked where they have worked in the plant. They all did work in one particular building at one time, but not their full life history in the plant. There are four polymerization areas at the Louisville plant and these people had worked in more than one. They had worked also in areas outside the polymerization areas.

MS. GHOLSTON: I'd like to ask you: have you noticed or found that there is any difference in the exposure of the employees to vinyl chloride or polyvinyl chloride depending on the stage of production that they're working in?

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MR. VITTONE: Well, not currently. There has been in the past years, and normally in the summertime the level would have been lower than in the wintertime due to less ventilation, closing of windows.

MS. GHOLSTON: Have any of your employees at any of your other plants other than the Louisville plant been found to have died of any other types of cancer other than angiosarcoma?

MR. VITTONE: Dr. Johnson, can you answer that?

DR. JOHNSON: Oh, yes. Over the years, surely.

MS. GHOLSTON: Have you made any connection?

DR. JOHNSON: The distribution, at least superficially, appears to be perfectly normal. Of course, there are too few to be meaningful, and that data is becoming a part of the Tabershaw-Cooper study in order to get enough data together to draw some meaningful conclusions.

MS. GHOLSTON: Are you making any distinction in trying to gather additional information between the vinyl chloride plant at Calvert City, I believe, and your polyvinyl chloride plant?

MR. VITTONE: The vinyl chloride plant at Calvert City has the same program as our polyvinyl chloride plants, as far as studying the employees and the health practices and so forth.

MS. GHOLSTON: Now, with respect to the other

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chemicals that are involved in the processes, are you going to do anything to determine whether or not some of the other chemicals may be carcinogenic?

MR. VITTONE: This is a decision we have not come to yet. The exposure level of other chemicals, of course, is much lower than vinyl chloride, for which they will be, I'm sure, studying the literature.

MS. GHOLSTON: Thank you.

JUDGE MYATT: Yes, sir?

DR. JAEGER: Jaeger of Harvard.

You did comment that all four workers had a ten-year work history with vinylidene chloride?

MR. VITTONE: Yes, I did.

DR. JAEGER: You were making then polyvinyl chloride, polyvinylidene chloride propolymers of polyvinyl chloride?

MR. VITTONE: Yes, it was a propolymer.

DR. JAEGER: Two questions -- one question, really. Vinyl chloride has been acknowledged to be a contaminant of polyvinyl chloride after it has been dried and sprayed or when it's about to be bagged. Is the same thing true of vinylidene chloride? Is it also a contaminant? What I'm asking is: what is the likelihood of vinyl chloride and vinylidene chloride in workers handling the material following polymerization?

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MR. VITTONE: Well, there is some vinyl chloride. I'm not aware of the vinylidene chloride content. I assume Mr. Crider might have some data on that.

MR. CRIDER: No, I don't. I couldn't answer the specific question. I don't know the answer to that right now.

DR. JAEGER: We have heard that vinyl chloride workers have developed angiosarcoma, but the way the story is coming out, we forget the rest, vinyl chloride and vinylidene chloride may develop angiosarcoma.

MR. VITTONE: Yes, there is exposure to other chemicals, as I pointed out in my testimony, to vinyl chloride, to vinylidene chloride, reactors, and so forth.

DR. JEAGER: Could you tell me the amounts of each compound that may constitute the exposure?

MR. VITTONE: It's almost impossible at this point in time to try to determine what the level of exposure was in the last twenty or thirty years, and that's what you're asking me to do.

DR. JEAGER: Your methodology for assessing vinyl chloride concentration in the work area, will it differentiate between vinyl chloride and vinylidene chloride and vinyl acetate and methyl alcohol? What I'm asking you there is: How intensively are you monitoring the exposure of your workers?

MR. VITTONE: The monitoring system we're using

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now will totalize all of those products. We're using a hydrocarbon system. So that when I say under 50 parts per million, the total is under 50.

DR. JAEGER: Thank you.

JUDGE MYATT: Are there any other questions?

Yes, Mr. Bien.

MR. BIEN: Do you have any information regarding the particle size of the polyvinyl chloride tests that you made in the different process areas at the PVC plant? I'm talking about PVC dust.

MR. VITTONE: You're asking for the size of the PVC dust?

MR. BIEN: Right.

MR. VITTONE: This varies with the process. Let's see if Mr. Crider has this in mind.

MR. CRIDER: No -- well, if you take all of the polymers that we make, there's a very wide range of particle size. Right off the top of my head, I couldn't take -- right now, I couldn't take a specific resin and give you a particle size number.

MR. BIEN: I'm talking about airborne dust size. I'm not talking about the size of --

MR. CRIDER: If you're talking about airborne particle size, the answer is I don't know.

MR. VITTONE: It's certainly below 325 mesh. It's

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pretty fine.

MR. BIEN: If you pass it through the screen size (inaudible) the mechanical process. We're just looking for this type information.

MR. VITTONE: Let me understand you correctly. You want information on the particle size of the real fine material?

MR. BIEN: In the airborne stage.

MR. VITTONE: I'm sure we have such data available and we'll make it available to you.

MR. BIEN: During the storage of your final product, like the resins, do you have any measurement of the vinyl chloride concentration in the storage silos or in the packages?

MR. VITTONE: In the storage silo? Yes, we have measurements there. I don't have it handy. But I would say they're probably on the order of a hundred or two hundred, that magnitude, in the silo -- you're talking about the closed silo?

MR. BIEN: You have four major products that you make in the PVC polymerization process (inaudible)?

MR. VITTONE: I don't quite understand your question.

MR. BIEN: During the normal operation you have a different polymerization process, bulk, suspension, emulsion.

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Which products will give the most exposure to vinyl chloride during normal operations, and how do you use them in emergency situations?

MR. VITTONE: You're asking me for exposure levels? I'd have to say that we keep them all within about the same level.

MR. BIEN: Thank you.

MR. VITTONE: There's maybe a difference between one plant and the other, but I don't think it's due to the processes.

JUDGE MYATT: Are there any other questions?

All right, gentlemen. Thank you very much.

The next witness to appear, Mr. Richard J. Reynolds of the Shell Chemical Company.

RICHARD J. REYNOLDS

MR. REYNOLDS: Mr. Chairman, my name is Richard J. Reynolds, Manager of Vinyl Chloride, Shell Chemical Company.

I am accompanied here by Mr. Howard L. Kusnetz, Manager of Industrial Hygiene, Shell Oil Company, and Dr. R. L. Maycock, Manager of Environment and Safety, Shell Chemical Company.

The Shell Oil Company and its division, the Shell Chemical Company, are pleased to be able to participate in this fact-finding hearing on the possible hazards of vinyl chloride manufacture and use. We are especially appreciative

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that the U. S. Department of Labor called this hearing before publishing any proposed regulation.

Shell Chemical Company manufactures vinyl chloride monomer, which we abbreviate VCM, at Deer Park, Texas, near Houston, and at Norco, Louisiana, near New Orleans. We entered the vinyl chloride industry only recently and we produce only the monomer, VCM. Our remarks will be limited to this segment of the industry only.

Shell's facilities comprise large, continuously operating process units closely integrated and requiring minimal manual attention or exposure to feed and product streams. Production in the unit at Deer Park, Texas, was started in August 1971. Production in the Norco unit was started in October 1973. Design production capacity is about 1,200 tons VCM per day at Deer Park and about 1,000 tons VCM per day at Norco.

At Deer Park about twenty persons are involved directly in the day-to-day operation of the VCM unit. Approximately twenty-five additional employees are involved less continually with VCM manufacture during the regular performance of their duties in maintenance, shipping, and supervision. Thus, at Deer Park about 45 workers out of a total chemical plant staff of 1,300 are concerned with VCM manufacture on a regular basis.

At Norco a similar number of direct VCM workers are

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required, but fewer shipping personnel, so about 25 workers of a total chemical plant staff of about 370 are involved on a regular basis with VCM manufacture.

The principal raw materials used in our VCM production units are ethylene and chlorine. At both Houston and Norco the ethylene is received by pipeline. Chlorine at Houston is received by pipeline and at Norco by railroad tank car. Small quantities of dichloroethane are received at both locations by barge to supplement these primary feeds. At Houston small supplemental quantities of hydrogen chloride feed are received via pipeline and tank truck.

The process technology employed at both Shell VCM units was licensed from Stauffer Chemical Company. In this process, about half of the ethylene and all of the chlorine fed are reacted to form the main intermediate, which is 1,2-dichloroethane. After purification, 1,2-dichloroethane is heated in a furnace to form product VCM and the main byproduct, hydrogen chloride. The product VCM is purified to greater than 99.9 percent purity by distillation and stored as a liquid under its own vapor pressure. The byproduct hydrogen chloride is recovered by reaction with the remaining half of the ethylene feed and with air to form additional 1,2-dichloroethane.

Minor byproducts of the process include carbon oxides, chloroform, carbon tetrachloride, ethyl chloride,

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the isomeric dichloroethylenes, the isomeric trichloroethylenes and trichloroethanes, tetrachloroethanes, and the isomeric chlorinated butanes.

The process is a continuous one. The reactants, intermediates, byproducts, and product VCM are contained within the process equipment in a closed system except for a continuous stream of waste process nitrogen which is vented from a high stack after water scrubbing. Occasionally there may be minor vents such as from loading arm drainage or leaks. The process equipment is opened only for maintenance, and then only after washing followed by purging of feed, product, or byproducts contents. Maintenance operations are generally infrequent; maintenance shutdowns are scheduled only once or twice a year.

The general precautions for containing and purging organic materials in large chemical process equipment are well-known to us as a result of our long history of manufacture and handling of flammable materials and chlorinated compounds.

When the process technology was licensed, a substantial compilation of toxicological information on VCM and associated feed and byproduct compounds was received from the licensor. Also we had available considerable other toxicologic information dealing with compounds already handled by Shell Chemical such as chlorine, ethylene, and ethyl chloride.

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This information is available to the public in toxicologic reference works; therefore, we'll avoid requoting it here.

Initial review of the VCM process toxicology information available to us in 1969 and 1970 led us to conclude that additional studies of our own were not required. Thereafter, in a paper delivered at the 1970 International Congress on Cancer by Viola, it was reported that tumor development was observed in rats exposed repeatedly to high concentrations of VCM. The exposure levels in the Viola work, 30,000 parts per million, were grossly in excess of published standards.

Nevertheless, the report raised a new concern as to what hitherto unknown effects might be expected with exposure to lower levels. Thus, we accepted an invitation by the Manufacturing Chemists Association to participate with others in the industry in sponsoring an exposure study to elucidate the possible effects of VCM at much lower levels and to participate in an epidemiology study. These programs were described in detail to you by the Manufacturing Chemists Association today. Shell Chemical has provided financial support and has participated actively in these programs from the outset.

From the time our Deer Park unit began VCM production in August of 1971 until early 1973, periodic spot measurements were made of the ambient plant air in the

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operating unit using standard colormetric VCM detector tubes. All measurements were well below the OSHA 500 ppm ceiling level and the 200 ppm time-weighted average Threshold Limit Value set by the ACGIH in June 1972.

From previous experience with other volatile and flammable materials, we were confident that the plant ambient air contained less than 200 ppm VCM, but this could not be verified because the detector tubes are not sensitive to much lower values. It was apparent that a new analytical method would be required to measure low levels of VCM and also that improved sampling techniques would be required to compensate for the greater effect of variances introduced by weather conditions and sampling locations at low levels. Therefore, a sensitive gas-chromatographic analytical technique for VCM in air was developed and sampling was modified to meet the needs of the situation. A copy of the method is appended to our submission.

Based on a developing concern and with the new analytical tools, our company elected to establish an internal working level of 50 parts per million, eight-hour time-weighted average, maximum exposure to VCM concentrations in air. This level and the possible implications and incentives for minimizing exposure indicated by the Viola work were discussed with our employees in July-August 1973. On August 15th, 1973, we formally advised all of our customers of --

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customers of our new working level and the reasons for it. A copy of our letter to our customers is attached.

Along with the new sensitive analytical technique we had our workers periodically wear an improved device for taking a continuous sample over eight hours of the air in worker's breathing zone. Results with the improved sampling and measurement technique showed no values in either VCM plant location exceeding the 50 parts per million VCM eight-hour time-weighted average. Special tests were also made to ascertain the maximum VCM exposure a worker might receive under abnormal conditions at the jobsite. Under some of these conditions, we found values of 100 to 200 parts per emission VCM, but these concentrations persisted only for a short time. Based on these tests, additional precautions and directions were put into practice.

In 1973 we began a program of medical surveillance of VCM workers who would be regularly assigned to jobs involving potential or regular exposure to VCM. Twenty-five workers at Norco were given the examination described below. Forty-two examinations will have been given at Deer Park when the current examination cycle is complete.

The annual examination provides for: (1) medical history; (2) physical examination by a physician; (3) laboratory blood studies including RBC, hematocrit, hemoglobin, WBC, differential count, and platelet count; (4) SMA-12 blood

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chemistry including serum bilirubin; (5) routine urine examination; (6) 14 by 17 P-A chest x-ray.

Based on existing knowledge, with the very low accumulated exposure of our workers to VCM, we would not expect these examinations to provide any data beyond that establishing a baseline for subsequent medical history. In fact, to date we have found no liver damage or cancer among the Shell participants. Although we have not been onstream long enough to have meaningful epidemiological data of our own, Shell Chemical is a financial supporter of the Manufacturing Chemists Association epidemiology study contracted to Tabershaw-Cooper Associates and described to you today.

In addition to the above actions, we continue efforts to locate and curtail emissions, should they be found, throughout our process units and associated loading areas.

With respect to Item 6 in the notice of this hearing, Shell Chemical would favor the route of the regular rule-making under Section 6(b) of the Occupational Safety and Health Act for a VCM standard as opposed to an Emergency Temporary Standard. The rule-making procedure would allow the orderly development of data.

Thank you very much for the opportunity to appear.

JUDGE MYATT: All right, sir. Shell Chemical Company's exhibit will be designated Exhibit No. 10.

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(Whereupon, Exhibit No. 10 was marked for identification and was received in evidence.)

JUDGE MYATT: At this point are there any questions?

MS. GHOLSTON: Has there been any change in the purity of the vinyl chloride that you used at the beginning up until now?

MR. REYNOLDS: No, our standards have always been 99.9 percent plus purity.

MS. GHOLSTON: With respect to any other chemical that may be involved in your process, are you looking to see if any other chemical might be a cause of cancer?

MR. REYNOLDS: As I mentioned earlier, we don't have our own toxicological studies, animal studies, of what's going on in our operations. I would say that we would support and feel that it would be advisable for the industry broadly to support additional studies and we would be glad to participate in that support.

MS. GHOLSTON: Thank you.

JUDGE MYATT: Yes, sir?

MR. ROSE: Mr. Rose from NIOSH.

Concerning the new environmental sampling system that you've gone to to replace the detector tubes, first of all, I assume it's an environmental sampling as opposed to personal sampling?

MR. REYNOLDS: It's both.

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MR. ROSE: It's both. Is this grab samples that are then analyzed in the gas chromatograph or are these --

MR. REYNOLDS: Well, we have done both studies. We feel that the most reliable indication at any point is given by the worker-carried apparatus which continuously pumps air for the duration of his exposure and collects it in a huge bag, and then this bag is taken to the laboratory and analyzed and it permits a pretty thorough analysis. It gets around the problem of differences owing to wind shift. It would be difficult for us to say -- we're in an open place -- where is the best place or the best five or six places to locate a detector. We just don't know where to put them.

MR. ROSE: One last question: you said he carries a sampling bag which collects the eight-hour sample. What's the bag made out of, the material, and have you run tests to determine the diffusion coefficient or loss through the bag material for vinyl chloride monomer?

MR. KUSNETZ: Yes, the bag is teflon and the tests have been done on diffusion, on bag memory, on other loss. Essentially, it's a personal sampler which can be run any period of time up to eight hours, and, so, you get a true breathing zone representative integrated sample of the individual worker.

JUDGE MYATT: Are there any other questions?

MR. MAZZOCCHI: Tony Mazzocchi, Oil, Chemical and

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Atomic Workers.

Have your employees, vinyl employees, ever been told of the possible relationship between VCM and cancer?

MR. REYNOLDS: Yes, they certainly have. As I mentioned, last July we mentioned to all the workers the Viola work -- of course, the Viola work didn't mention liver cancer, but we did warn the people that this was a very great unknown area and we were concerned about the possibility, and that's why we called the meeting, to solicit their cooperation with us to do some of the personal sampling.

MR. MAZZOCCHI: My question was: was any specific reference made to liver cancer and VCM?

MR. REYNOLDS: Oh, yes. The day the Wall Street Journal article appeared announcing the disclosure by B. F. Goodrich Company, one of our plant managers tacked the copy of the Wall Street Journal on the bulletin board so that all could see it, and the assistant department manager in our VCM unit met every shift who came into the plant that day and told them of the article and re-emphasized the need for precautions.

MR. MAZZOCCHI: Prior to the Wall Street Journal article which appeared, no mention was made of the relationship -- possible relationship between liver cancer and VCM?

MR. REYNOLDS: We suggested there may be evidence -- there was no evidence of liver cancer before the Viola

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article, but in animals -- weren't there animal tests? -- I'm sorry, maybe I don't understand your question.

MR. MAZZOCCHI: I understood the reply, so let me--

JUDGE MYATT: Let's go to the next question, please.

MR. MAZZOCCHI: Are employees told of the monitoring results by the unit employees monitoring the results after the analysis is made?

MR. REYNOLDS: Yes. Each employee -- the ones who wear the personal monitoring device receives the results that he produced during the time that he wore the device.

MR. MAZZOCCHI: After it goes through analysis, then he's told?

MR. REYNOLDS: Yes.

MR. MAZZOCCHI: Does Shell release to the physician of the employee's designation the results of the physical examinations that you give these employees?

MR. REYNOLDS: The employees are told the results of the physical examinations individually.

MR. MAZZOCCHI: And you release this information to the designated physician if the employee so requests it?

MR. REYNOLDS: Yes, we have.

MR. MAZZOCCHI: I have just one other question. I'm not quite clear. Was a liver scan given as part of that protocol? I might have missed it.

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MR. KUSNETZ: No, the liver tests were the SMA-12s -- were included in the SMA-12s.

JUDGE MYATT: Yes, sir?

MR. COTTINE: I'm Bertram Robert Cottine. I'm from Health Research Group.

Mr. Reynolds, you mentioned the MCA epidemiological study. Could you indicate to us the cost of that total study and the participation of Shell in it in terms of its part? In other words, the cost of the total study and your contribution.

MS. GHOLSTON: I object. I don't see the relevancy of the cost to this proceeding.

JUDGE MYATT: I agree. I'm sorry, sir, but I'm not going to require him to answer the question. That has no bearing on the issue before us.

MR. COTTINE: What is the nature of review of the participant companies over the course of that study? What type of review committee is established and are you a participant or do you know the participants?

MR. REYNOLDS: Yes, we are a participant. We know the participants. But I think that is a more proper question for the MCA. I defer....

MR. COTTINE: Your Honor, could we request that he provide us as much information as he, of his own knowledge, knows regarding the conduct of those committees? The

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protocol review is extremely important to the subsequent results in the proceeding.

JUDGE MYATT: It would seem to me that that's more properly directed to MCA.

MR. COTTINE: Your Honor, as you well know, we were not capable of cross-examining this morning by virtue of your ruling.

JUDGE MYATT: Have you made a request of MCA?

MR. COTTINE: No, we have not.

JUDGE MYATT: I would suggest you do that.

MR. COTTINE: On August 15th, 1973, you mentioned that you advised your customers of your new working level and you briefly stated the rationale. What was the nature of your previous communication with your customers and what did you advise them regarding the vinyl chloride and polyvinyl chloride?

MR. REYNOLDS: All our previous advice was based on the then published standard, which was the OSHA 500 standard, and the recommended ACGIH 200 standard.

MR. COTTINE: Did that include any printed material of your company regarding those particular standards?

MR. REYNOLDS: Material Safety Data Sheets were available. I can't say precisely who got what.

MR. COTTINE: Have you submitted those particular Safety Data Sheets for the record?

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MR. REYNOLDS: I have submitted our latest Safety Data Sheet as part of our record.

MR. COTTINE: May we respectfully request that you submit the earlier Safety Data Sheets as a part of the record?

MS. GHOLSTON: Could I ask Mr. Cottine what the purpose of the earlier data sheet would be?

MR. COTTINE: Yes. We would like to know the comparison between the two different safety data sheets and the rationale in terms of the health hazard involved.

MS. GHOLSTON: Then could I ask a question of the witness?

The previous data sheet, did it have any reference to the carcinogenicity of the vinyl chloride or was it based on the toxicity?

MR. REYNOLDS: The previous sheets were based on the previous information which was known to me. The latest sheet does specifically mention the Viola study and the potential dangers.

MS. GHOLSTON: Do you have any objection to introducing them?

MR. REYNOLDS: I am willing to introduce our latest safety data sheet, and I think I must say that we should revise even that sheet in the light of the B. F. Goodrich results, and, so, I'll introduce the sheet that we have and tell you that we're going to revise it further to more

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specifically indicate what B. F. Goodrich has told us today.

JUDGE MYATT: What is the position of the Solicitor in regard to the prior safety sheet?

MS. GHOLSTON: As far as we're concerned, it would be information, but he's indicated that as far as a carcinogistic, it has no bearing. However, for our purposes, we might like to look at it.

So, unless you have a specific objection to introducing it -- and I don't think you stated one --

MR. REYNOLDS: I'll have to reply to you in writing on that subject, if you please. I don't know what our availability is.

MS. GHOLSTON: That's fine. I don't know about Mr. Cottine.

MR. COTTINE: I would request, Your Honor, to have it submitted, but if you do it voluntarily....

I have one further question. Now, you have already the August 15th, 1973, advice as part of the record; that is correct?

MR. REYNOLDS: Yes.

MR. COTTINE: Will you be submitting as a part of the record any subsequent revisions?

MR. REYNOLDS: Would you please say your question again?

MR. COTTINE: You noted that after the B. F.

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Goodrich testimony of this afternoon that you would probably be revising the August 15th, '73, letter to your customers. Are you submitting that revision?

MR. REYNOLDS: If that would be of interest to the group here, we would. I think we feel compelled to do so.

MR. COTTINE: Thank you.

JUDGE MYATT: Yes, ma'am?

MS. HRICKO: Andrea Hricko.

You said that you monitored from '71 until August of '73 (inaudible), and then on August 15th of '73, you revised your sheet to your customers describing your new working level, why you changed it. I don't understand what prompted the revision, why you lowered the working level.

MR. REYNOLDS: I'll try and respond, if I understand the thing. The thing that prompted us to revise our own internal thoughts and notify our customers was a general developing concern, much of which was shared by other people who participated in the MCA study. We elected, in view of this rising concern and uncertainty, to review our standard and we went back to the basis, the TLV documentation basis, which was set forth in their establishing the lower level of 200 parts per million TLV. In examining the background cited by that background -- in that ACGIH background study, we noted that it referred to recommendations in the literature varying all the way from 50 parts per million to 500, and

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since we didn't know anything further, we elected to take the more conservative level, and that's why we decided to take the 50 level, and that is so stated in our letter which is appended to our submission.

MS. HRICKO: Thank you.

JUDGE MYATT: Are there any further questions?

All right, gentlemen. Thank you.

Our next presentation is going to be rather lengthy, so we're going to take a five-minute recess.

(Whereupon, a short recess was taken.)

JUDGE MYATT: Let's come to order, please.

For the benefit of those who are going to have to catch planes or leave for other reasons, we are in the process of determining a date which we are going to keep the record open. At this moment that date has not been established. It will be before this hearing is adjourned, and any further submissions which the parties would like to be included in the record, you are to address to the Occupational Safety and Health Administration, Room 240, 1726 M Street, N. W., Washington, D. C. Zip 20210.

But again I repeat that before this hearing is concluded, we will establish a date to which we are going to keep this record open for any additional submissions.

All right. The next group testifying consists of Mr. Sheldon Samuels, Director of Health, Safety and

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Environmental Affairs of the IUD, AFL-CIO. Accompanying him will be Dr. Henry Anderson, Mount Sinai School of Medicine, Dr. Thomas F. Mancuso, University of Pittsburgh Graduate School of Public Health, and Mr. Louis Beliczky, Director of Industrial Hygiene, United Rubber, Cork, Linoleum and Plastic Workers, AFL-CIO.

Gentlemen, proceed.

SHELDON SAMUELS

MR. SAMUELS: Thank you.

Let me say I have no introductory remarks per se, but I would like to note that if a unique tumor had not been involved, as was noted earlier this week, the effects that we've been discussing all day would still not be noted and no action taken. It seems that we pay the price each day in lives and lost production for our continual neglect of systematic research and case finding.

I'd like to introduce Dr. Thomas F. Mancuso, who on February the 1st represented our Department in a meeting noted earlier by Mr. Rose as a consultant to the Industrial Union Department, on my left, and on my right, Mr. Louis Belicsky, who is, as you have noted, the Director of Industrial Hygiene for the United Rubber Workers. He attended that meeting, also, representing his president, Peter Bommarito, who is the chairman of the committee on the health and safety of workers of the Industrial Union

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Department.

And on my far right is Dr. Henry Anderson, who is a clinical consultant to the Industrial Union Department and, as has been noted, is on the staff of the Mount Sinai School of Medicine.

Dr. Mancuso will begin for us.

THOMAS F. MANCUSO, M.D.

DR. MANCUSO: I'm Thomas F. Mancuso, Research Professor of the University of Pittsburgh Graduate School of Public Health.

A new occupational cancer has been identified. The presentation I am making is at the request of the Industrial Union Department of the AFL-CIO. I prepared the following statement in support of their request for an emergency temporary standard to be issued by the Occupational Safety and Health Administration.

It is my considered opinion that appropriate steps be taken to provide for immediate protection of the workers exposed during the manufacturing processes concerned with the polymerization of vinyl chloride.

I have also made additional recommendations for consideration by the Secretary of Labor.

The worldwide manufacture of polyvinyl chloride, now identified with the association of cancer, brings up a tremendous range of human, social, and economical problems.

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The immediate pressing question is whether the cancer observed will be confined to the manufacturing process or also occur in successive lower grades of exposure in the processing and use of vinyl chloride and polyvinyl chloride and whether other types of cancer may subsequently be identified.

The potential magnitude of the cancer problem, however, does not rest on vinyl chloride alone, but, rather, on its role as a possible index cancer chemical as an indicator to a large group of similarly structured chemicals. Should any of these chemicals prove to be carcinogenic, then the magnitude of the risk would extend to an ever widening circle of industries, processes, and exposed populations. The degree of validity of these various possibilities must be identified and resolved.

Invariably, whenever a new occupational cancer is discovered, it is played down for fear of alarming the workers and the general public. The motivation may be one of not really knowing the facts. Nevertheless, from past experience what happens is that as further work is undertaken and information obtained, the problem gets broader and broader with more implications. I think a more straightforward approach to the workers and the general public is warranted, citing the limitations of what we do not know, clearly indicating what the situation is, what efforts are being

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developed and carried out to determine the scope of the problem and to correct it.

The scientific unknowns. This situation, the chance recognition of an occupational cancer by a unique combination of circumstances, clearly demonstrates what is not known about the carcinogenic potential of thousands of industrial chemicals that have been in use for decades and further focuses attention on the total absence of a national concerted study of occupational cancer in this country.

The serious national question that is raised and not resolved, because it is either too shocking to contemplate or because the agencies responsible for the protection of the public are reluctant to open this complex Pandora box, is, in essence, that a national study directed at the industrial environment might uncover a whole series, a succession of occupational cancers, which in turn would implicate in the distribution of these chemicals a larger and larger portion of the population exposed to the risk of cancer. It is my understanding that there never has been any legal requirement that the industrial chemicals in the work environment be tested for their cancer-producing effects. With thousands of industrial chemicals involved, conservatively estimated at 20,000, the real carcinogenic potential of these chemicals acting alone or in combination with each other has never been established.

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Further, there are indications that previous methods of testing industrial chemicals may not have been adequate nor sufficiently sensitive nor were all the substances tested for carcinogenic effect. At this point I should like to make the difference between testing for toxicologic effect and for carcinogenic effect, and invariably in the past the primary emphasis was relative to the toxicological effect. In addition, they were invariably tested as a single chemical rather than in combination of chemicals used in the work environment.

The short-term laboratory experiments previously used and the primary use of ingestion or injection in experiments rather than inhalation exposure, which is the particular means of exposure to the worker, have definite limitations as accurate assessments of cancer risk to the worker.

Invariably, the chemicals tested in animal experiments are at room temperature, yet when these chemicals are used in industry, they may be subjected to heat and may change their composition or unite with other chemicals in the work atmosphere to form new chemicals whose carcinogenic and toxicological potentials have not been identified. No one really knows the carcinogenic potential of the complex occupational environment in the United States.

In the face of these scientific unknowns, how can anyone arbitrarily assume, as has been consistently done in

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the past, that occupational cancer is a minor problem? Such arbitrary assumptions in past have been responsible for the absence of the necessary investigative studies of the work environment by the Federal Government.

This is a vicious cycle in which the assumptions preclude the studies, and without the data the assumptions remain. If the studies had been done, the original assumptions would be found to be grossly false and the scientific misunderstanding that has been maintained over the years would be reversed.

At present the attention is now focused on the vinyl chloride process and undoubtedly a concerted effort will be undertaken and must be undertaken. The question I am raising is: must the industrial population and the general public wait until each particular cancer is identified by accident or is forcibly brought to our attention in some other means before a concerted effort is undertaken to determine the magnitude of the problem, its cause, and control? It would be more appropriate, in my opinion, to utilize this observation of occupational cancer to focus attention on the need for a national study by the Center for Communicable Disease -- the Center for Disease Control, NIOSH, and the National Cancer Institute, and all other agencies in a concerted effort directed at all suspected carcinogenic chemicals in the work environment. In addition,

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the development of an industrial epidemiological cancer surveillance recognition system for this purpose is required.

Duration of employment and latent period. The implications throughout this testimony -- the implications of the statement that all men who died of angiosarcoma had at least fifteen to sixteen years of exposure in the manufacturing of polyvinyl chloride should be critically assessed. No one knows at this early stage what combination of length of exposure, concentration or contact with the polyvinyl chloride process will cause the specific angiosarcoma.

In occupational cancer, the actual exposure in terms of length of employment may be very small. It is the latent period, that is, the interval period between each exposure and the development of the cancer, that may take many years. In essence, no one knows for the four cases of angiosarcoma if the induction of cancer to this type of carcinogenic agent requires relatively few years of exposure and a further latent period of twelve years or more or whether the induction does require fifteen years of exposure.

In my opinion, based on other occupational cancers, it is most unlikely that the carcinogenic dose would require fifteen years of exposure. The relatively young ages of the four cases of angiosarcoma, 37, 43, 50, and 55, and the rapid progression of the cancer once it is identified clinically, six months to three years, indicates a strong carcinogenic

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agent and/or in conjunction with some other harmful chemical agent.

Industrial causes for cirrhosis of the liver. The observation among another group of four workers in this small employment group of cirrhosis of the liver, non-alcoholic, confirmed by eminent pathologists, is very important as another manifestation of occupational disease for those exposed to polyvinyl chloride processes.

The significance of these cases of cirrhosis of the liver is to make the medical profession and the general public more aware that there are industrial causes for cirrhosis. This observation should further serve to underscore the need for a large scale study to uncover other industrial causes of cirrhosis. The question is, however, how many cases of cirrhosis of the liver due to vinyl chloride processes and other industrial chemicals have gone unrecognized.

The additional implications of cirrhosis of the liver are the effect on the employability and the lifespan of the worker. The normal capacity and function of the liver to detoxify chemicals taken into the body are impaired by cirrhosis. Consequently, this effect of cirrhosis would severely limit subsequent employability, as well as lessen the capacity of the worker to recover from other illnesses and diseases which may occur in subsequent years.

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If, in the subsequent review of microscopic slides of cirrhosis of the liver, there is found an indication in some areas of the liver of atypical cell changes toward malignant formation, then cirrhosis of the liver may be seen specifically as an increased risk in the development of liver cancer for the workers exposed. This does not mean, however, in any way that all cases of occupational liver cancer would require the precursor mechanisms of cirrhosis of the liver or that the two diseases must always be present together. The question and objective remains: what is the minimal induction dose in terms of duration of employment and concentration of exposure to VC and PVC to incite the development of cirrhosis of the liver?

Possible other health effects. Further, no one knows what other types of illnesses or other cancers may occur. Consequently, the investigations undertaken should be all-encompassing and of all systems and organs and not confined to angiosarcoma of the liver. The experimental observations of rats exposed to vinyl chloride demonstrated cancer of the skin, lung, and bone, and in another study angiosarcoma. And now, with the information provided this morning so excellently, the information relates to cancer of the kidney, and it indicates the importance of studying other systems of the body.

Although the focus is now on the experimental

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cancer-causing effect, it is very important to note that other pathological changes occur in the brain, degeneration of the nerve cells, of the cerebellum; severe chronic hepatitis, besides the cirrhosis; interstitial pneumonia, and damage to the kidneys, and it is also possible that coronary heart disease or some type of heart disease may be involved.

Further, the skin tumors frequently developed near the ear and submaxillary or the same areas as the salivary glands. It was postulated by the original investigators that vinyl chloride may enter the salivary gland system. If this is subsequently confirmed, it raises the question whether tumors of the parotid gland can also occur, as has been demonstrated in the rubber industry -- and this has been confirmed now by the testimony this morning, that cancer of the parotid gland has been observed in animals.

These various facets are mentioned primarily to broaden the approach undertaken in the evaluation of the health risks involved. The present concentrated attention on angiosarcoma might inadvertently miss other related health problems including other organs and systems. Similarly, negative results from a comprehensive study would be more reassuring than an investigation confined to one organ of the body.

Medical evaluation. The actual and potential

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health effects identified by clinical and experimental observations have clearly established the need for comprehensive medical programs for the protection of the workers in the vinyl chloride and polyvinyl chloride operations.

The Federal Occupational Health and Safety Act requires that the health of the worker not be adversely affected during his employment and this, therefore, places the responsibility on industry to ensure that no harmful effects do occur as a result of exposures to the various chemicals and the work processes involved.

Unless the polyvinyl chloride plant is providing adequate and effective medical examinations, there is really no way of determining whether harm is being done until the harm has become a reality. Similarly, unless medical examinations and special tests are provided periodically, occupational health effects will not be recognized, in particular those that occur as a result of accumulated exposures or peak exposures at different points in time or as a result of changes in the work processes. For vinyl chloride, the range and scope of general and specific tests that should be conducted relative to the specific organs and systems that might be affected should be given careful consideration. The responsibility for the provision of the tests would rest with the industry.

The recognition of occupational health effects

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depends upon the physicians and unless they are available to see the workers, to hear and know their symptoms, and provide the examinations and special tests, occupational diseases will not be identified at their earliest stages nor, unfortunately, even at the most advanced stages or at all.

Arrangements should be made so that all medical observations relative to the health status and any changes in the status of each worker should be made available to his personal physician. There must be a certain quality or standard of performance relative to the completeness of the examinations and the types of tests performed and, therefore, the specification of whatever tests are determined should be clearly delineated.

It is essential that the basis for linkage of medical and environmental data -- for the individual plants, medical examinations by medical physicians alone without accurate and complete records are not effective. It is essential that the basis for the linkage of medical and environmental data be established so that correlations with environmental exposures and specific work processes and the recognition of an occupational illness can be made. When a group of workers employed in the same department or work process, exposed to the same chemicals, come down with the same pattern of symptoms or illnesses, then the essential criteria for the recognition of an occupational disease have

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been met.

The worker should be informed directly as is required by the Federal Occupational Health and Safety Act of the type of harmful effects that may occur with the chemicals he is working with, in this instance vinyl chloride and polyvinyl chloride, and the most effective ways in which the harmful exposures can be controlled and the best ways that he can protect himself. If the worker does not know what kinds of illnesses or injurious effects are caused by the particular chemicals he works with, then he will not be able to recognize the occupational illnesses when they do occur. In turn, unless the worker tells his doctor what chemicals and materials he has been exposed to, now and in the past, even his family doctor will not recognize that the illness or disability could be due to his work. The result is that occupational harmful effects are not being identified, recorded, investigated or corrected.

Work exposure. Exposure data in terms of air concentrations in the workplace and other means of exposure, such as due to contaminated workplace from breaks in equipment, poor housekeeping, inadequate ventilation, and absence of personal protective equipment, and so forth, are important in the ultimate correlation analysis of the degree of exposure to polyvinyl chloride and the subsequent health effects.

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Precise data on exposure is required as a basis for subsequent resolutions of what health effects occur at different levels of exposure and, finally, the exposure data determines the nature, type, and comprehensiveness of the control measures required.

The unfortunate lesson learned and demonstrated is that environmental monitoring is extremely important for the company, the worker, and the public. The dilemma now posed in the absence of such precise data is that the information the company, government, and scientists need to help resolve the risk factor is not available. The burden now falls to measuring risk in terms of health effects measured by crude exposure levels which, as already described, have questionable quantitative validity.

Problems of the epidemiological study. In referring to the "rarity" of angiosarcoma, such as twenty-one or twenty-eight cases in the U. S. in a specific year recorded only on the death certificates, this number should not be misinterpreted as an indication that no problem exists. Actually, it is a problem of a latent period and what is important is what has not been recorded or recognized. The problems, obstacles, and difficulties in the conduct of epidemiological studies of industrial cancer are substantial indeed. When the study is based solely on death certificates and involves a rare type of cancer, the problems of

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recognition are made even more difficult. When the cancer is confined to a specific histological type, the mathematical odds against the detection of angiosarcoma by death certificate alone are tremendous. In essence, the death certificate alone for the identification of this cancer would most likely provide "false negative" findings, and reliance solely on death certificates, therefore, would be inappropriate under these circumstances. As of now, based upon the four cases of angiosarcoma with the latent period estimated at fifteen years minimum, if the death certificates are used from the plants which have been in existence for less than fifteen years, then results, if any, will be further diluted.

There are a substantial number of basic limitations relative to epidemiological studies which I have in the document submitted for the report. I shall just highlight several of them. One relates to limitations of the death certificates themselves; the movement of employees to other cities; the extent and percentage of autopsies performed in the community; the availability of hospitals and pathology resources in the community; the limitations of what is recorded on the death certificates -- for example, in the case of beryllium disease, 74 percent of the individuals who were previously identified as having beryllium disease were not recorded on the death certificate; a death certificate may be completed before the autopsy is performed, or the

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microscopic review completed weeks later with no additional supplementation to the death certificate. Consequently, the cause of death on the death certificate may not specify the histological diagnosis, and this type of information would only be available through successive follow-up searches of pathological reports in hospitals. Workers who died of heart disease may also have had cirrhosis or cancer of the liver, but the cirrhosis or cancer of the liver was not recognized because no biopsy was done while he was alive nor at death.

And I should like to add parenthetically that one should be careful in evaluating the heart -- questions of heart disease because of some previous experimental work.

It is apparent in studying cirrhosis of the liver and angiosarcoma that many factors are in operation to underestimate what has happened and may be happening.

For the particular cancer now under consideration, I should like to caution that it would be most unwise to confine the recognition of occupational cancer solely to the histological type angiosarcoma. If other workers who are exposed to the same work processes of polyvinyl chloride develop the same disease, cancer of the liver, the cancer should be considered as occupational in origin regardless of the histological type. It must be remembered that cancer of the liver itself is an uncommon type of cancer.

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It is yet possible that other histological types of cancers may develop, as well as other health effects. We do know that in other industrial cancers, for example, lung cancers caused by chromate and asbestos, that the histological type of lung cancer are not specific, but, rather, may be different in workers of the same plant or occupations with the same years of employment.

Recommendations: 1. That the Government, referring to the Center for Disease Control and NIOSH, take the initiative and conduct its own independent extensive study of the cancer potential and health risks associated with exposure to polyvinyl chloride processes. Further, that the Government should undertake such steps as necessary immediately to apply its resources and expertise in epidemiological investigation and to seek such funds, if necessary, to carry out the national study.

2. That an International Research Committee on Vinyl Chloride and Cancer be organized with representatives of other countries. The committee would follow the pattern of the previous similar International Committee established for asbestos and cancer which was under the auspices of the UICC, the International Union Against Cancer.

3. That a Government conference of representatives of all the federal agencies who are concerned directly or indirectly with occupational cancer and the study of the

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industrial environment be convened so that an evaluation can be made of the resources and funds appropriated and the nature and extent of the various programs, efforts, and funds concerned with the identification and control of occupational cancer.

The fourth and final recommendation is that the international unions themselves, with whatever systems may be provided by the Secretary of Labor -- that the international unions assume as their major objective in conjunction with the universities and medical centers a concentrated effort to study the cancers which are occurring among members of their unions, the relationship to particular occupations, work processes, chemicals, and industries. The objectives go beyond vinyl chloride, to all industrial operations as a fundamental approach of case finding of occupational health problems.

Thank you.

JUDGE MYATT: Thank you.

MR. SAMUELS: I'd like to insert in the verbal record at this point to complement the testimony of Dr. Mancuso the following statement of the Surgeon General dated April 22nd, 1970: "No level of exposure to a chemical carcinogen should be considered toxicologically insignificant for man. For carcinogenic agents a safe level for man cannot be established by application of our present knowledge. The

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concept of socially acceptable risk represents a more realistic notion."

In the Occupational Safety and Health Act of 1970 the concept of socially acceptable risk is expressed in the concept of technical feasibility. We caution the Secretary to make no decision on any other basis. The past pattern of making these decisions on the basis of micro-micro economic studies is inadequate.

Mr. Beliczky.

LOUIS S. BELICZKY

MR. BELIZCKY: The --

MS. GHOLSTON: Could I ask --

JUDGE MYATT: No, not at this point.

MS. GHOLSTON: The reason I wanted to ask him now was not to get so far from the statement that he couldn't....

JUDGE MYATT: I understand. Not at this time.

MR. BELICZKY: I'm Louis S. Beliczky, Director of Industrial Hygiene for the United Rubber Workers International Union.

I am presenting this testimony to the Judge and the Secretary for Mr. Peter Bommarito, President of the United Rubber Workers International Union.

Section 6(c)(1) of the Occupational Safety and Health Act of 1970 instructs the Secretary to provide an emergency temporary standard if he determines, one, that

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employees are exposed to grave danger from toxic substances or agents and, two, that an emergency standard is necessary to protect employees from such danger.

The Director of the National Institute for Occupational Safety and Health has declared, in Cleveland on February 12th, 1974, that, based on information related to him by the B. F. Goodrich Company and his own investigation, the cause of at least four deaths due to angiosarcoma of the liver among former employees of the company's plant must be presumed to have an occupational cause. At an earlier meeting on February 1, 1974, he stated that "on the basis of medical, epidemiologic, and toxicologic findings thus far, it would appear that a new occupational cancer has been discovered associated with the polymerization of vinyl chloride in the manufacture of polyvinyl chloride. Vinyl chloride is the chief suspect..."

Approximately ten corporations and at least 6,500 production workers, organized by affiliates of the Industrial Union Department, are directly involved in vinyl chloride synthesis and its polymerization.

A task force of NIOSH, industry, and labor specialists convened on February 12th by the Director of NIOSH agreed that the process of vinyl chloride polymerization, including the production of vinyl chloride itself, must be presumed to be carcinogenic and that action should be

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taken for the sake of prudence in the public interest.

Actually, as the medical literature attached will indicate, vinyl chloride has been regarded by responsible investigators as highly toxic and probably carcinogenic in man for some time. Industrial practice at the B. F. Goodrich plant in Louisville and elsewhere has aimed at achieving one-tenth of the special limit value used by the Occupational Safety and Health Administration. Even that level does not meet criteria established by the Secretary of Health, Education and Welfare for exposure to a carcinogen.

Therefore, it is clearly the responsibility of the Secretary to determine that employees are exposed to grave danger in the polymerization process by which polyvinyl chloride resin is produced.

Based on information supplied by the B. F. Goodrich Company, an investigation of their plant in Louisville, Kentucky, and other information interim work practice standards have been transmitted to the company and to the Manufacturing Chemists Association. There is no indication that all these recommendations are being universally implemented, no determination that they have even been distributed to all plants, and there is no means by which employees can participate in or initiate compliance with these recommendations. Therefore, an enforceable regulation is necessary to ensure that employees are

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protected from such danger as vinyl chloride and its polymerization process.

Thus, the issuance of an emergency temporary standard by the Secretary is imperative.

Urgent action by the Secretary is necessary. As investigation proceeds in other countries and in plants other than that in Louisville, we are discovering diseases of the liver that are likely precursors to latent and developing cancer. Additional deaths from liver cancer are being uncovered that must be attributed to exposure during the production of polyvinyl chloride resin.

The probability exists that reduction in exposure among diseased workers will reduce the risk of liver cancer and that the identification of these workers may save their lives.

The Standards Advisory Committee on Carcinogens appointed by the Secretary proposed a scheme on August 23rd, 1973, that still represents, in our opinion, the best thinking applicable to the control of any carcinogen. We recommend that the Secretary accept that report, and it's attached, with the following changes appropriate to this situation, these are some of the changes:

The word "purpose." The purpose of this standard is to prevent any worker contact or exposure to vinyl chloride during its production and polymerization as detected

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by the most sensitive, feasible sampling and analytical methods available.

A change in scope and application. This section applies to any workplace in which the carcinogen is manufactured, processed, used, repackaged, released, handled or stored.

A change in terminology. Eliminate Subsection 1 and retain the balance of this subsection.

Another change in requirements for areas containing carcinogens. Eliminate Subsection 1, "or decontaminated" in (d), Subsection (2)(ii), "close to the point of exit" in (d)(2)(vi).

Because of the volatility of vinyl chloride, we do not believe that the installation of special shower facilities is necessary. Changes to reflect this would be appropriate. The medical requirements of the Advisory Committee need to be amended. Our recommendations are those of Dr. Anderson, clinical consultant to the Industrial Union Department, who will make his presentation after this.

We believe that all of the appropriate, specific interim recommendations transmitted by NIOSH to MCA be included with the recommendations of the Advisory Committee on Carcinogens.

Furthermore, in view of the information supplied us by industry representatives on February 12th, 1974, that

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500 to 3,000 parts per million of vinyl chloride may be entrapped in the polyvinyl chloride resin prior to packaging and shipment, it is essential that the concentration of vinyl chloride in the resin be reduced to less than 0.01 percent as quickly as possible.

Vinyl chloride, the monomer of polyvinyl chloride, is a gas with known anaesthetic effect in high concentrations. At the same high levels it is known to sensitize the heart resulting in fatal arrhythmias. There are at least two fatalities in acutely exposed workers reported in the literature. Dizziness, headache, disorientation are symptoms which may be the alarm sign for acute overexposure.

The chronic effects of vinyl chloride have been studied by Torkelson, et al., on laboratory animals, rats, rabbits, guinea pigs, and dogs. The results, published in 1961, emphasized the effects on the liver and kidney at concentrations of 500, 200, and 100 parts per million. The conclusion of that study stated, "Repeated exposure to vinyl chloride at concentrations considerably below the level that has been considered safe for human exposure, 500 parts per million, has been shown to have an effect on the liver and kidney of laboratory animals."

It was recommended that daily exposures should be limited to 100 parts per million, although this level would not offer any margin of safety. Industry sources claim that

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they have been successful in achieveing levels of 50 parts per million for many years in accordance with the preferred industrial hygiene practice of providing a margin of safety. The threshold limit value suggested by the ACGIH was maintained at 500 parts per million until recently when it was reduced to 200 parts per million. Five hundred parts per million is the current OSHA standard.

At this point we wish to commend Dr. Cesare Maltoni for his clarifying presentation this morning. His comments certainly affirmed our thinking regarding the carcinogenicity of the polyvinyl chloride polymerization process.

Before I conclude, I'd like to enter for the record the testimony that was submitted by International President Bommarito on September 11th, 1973, just a portion on the testimony regarding a standard for carcinogens, the closing of his remarks: "We demand the absolute need of a permit system for the effective implementation of an enforceable standard. I must emphasize the Standards Advisory Committee's recommendation: 'A use permit system shall be initiated as an integral part of the permanent standard to provide for effective regulation of conditions and practices concerning carcinogens to enhance the implementation of the standard.'

"II. The need of a National Registry of exposures

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to carcinogens. NIOSH's assistance in this area is envisioned."

Items I and II as mentioned here are also strong recommendations in Report VII of the ILO's 58th Session regarding the "Control and Prevention of Occupational Cancer.

Thank you.

JUDGE MYATT: For the record, Madam Reporter, Dr. Mancuso's statement will be Exhibit No. 11, the combined statement of Mr. Beliczky and Dr. Anderson will be designated as Exhibit No. 12, and the report of the testimony read by Mr. Beliczky will be designated Exhibit No. 13 in the record.

(Whereupon, Exhibits Nos. 11, 12, and 13 were marked for identification and were received in evidence.)

JUDGE MYATT: All right, Dr. Anderson.

HENRY ANDERSON, M. D.

DR. ANDERSON: I am Dr. Henry Anderson, Clinical Consultant, Industrial Union Department.

It is necessary that an effective medical examination protocol be established rapidly to provide a uniform means of initial and continuing surveillance of all workers in vinyl chloride and polyvinyl chloride operations.

It is recommended that a specific set of clinical and laboratory examinations be required periodically for every VC and PVC industrial worker. The following protocol

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of minimum medical surveillance requirements was developed in cooperation with the Mount Sinai School of Medicine, Environmental Sciences Laboratory. The protocol was carefully designed not to exceed the service capabilities of local community facilities. It is recognized that there are tests which are more specific, but which are not universally available. It is suggested that where available such tests would be incorporated by individual examining units.

The following protocol is recommended as the minimum acceptable initial and continuing periodic examination for all VC and PVC operation employees:

No. 1, history. The understanding of the natural evolution of disease associated with VC and PVC production will be aided by systematic, periodic records. Accurate records will help clarify the possible interrelationships of the various multiorgan-system clinical entities already described in the world literature, such as Raynaud's phenomenon acroosteolysis, cirrhosis, and other liver disease, pulmonary fibrosis, thrombocytopenia, and now hemangiosarcoma.

Thus a comprehensive work history covering all past and present employment with specific job descriptions and exposures, a complete medical history covering all organ systems, and all pertinent chemical environmental agents must be carefully recorded.

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A standard questionnaire and examination form should be developed and its use required so that examinations and records will meet a uniform quality. Such a form will assist the examining physicians who are not trained occupational medicine specialists.

No. 2, physical examination. Each worker should have a thorough, complete physical examination of all organ systems and have specific parameters properly recorded on the required examination form. Continuing periodic examinations should also be made.

No. 3, X-ray examination. It is recommended that each individual have a periodic 14 by 17-inch PA chest X-ray and X-rays of both hands. These should be read by experienced radiologists.

No. 4, pulmonary function tests. Vital capacity and one-second forced expiratory volume measurements should be recorded.

Blood tests. A complete blood count and platelet count should be done. An automated battery of SMA-type determinations of SGOT, SGPT, alkaline phosphatase, LDH, albumin, bilirubin, cholesterol, uric acid, glucose, BUN, and calcium should be included.

Urinalysis. Routine screening tests for glucose, blood, and protein should be done.

It is understood that where facilities are readily

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available to do more specific tests, they should be incorporated so that the examining physician has the best possible information available. The examining physician should add all available tests he feels would be useful.

It is recommended that the worker be given this protocol of examinations every six months. After the initial history, an interval history can update the record.

If a test is abnormal, it is recommended it be repeated within one month and if the abnormality persists, it should be further investigated using additional appropriate tests.

It is recommended that upon individual authorization, all company medical records be made available to his personal physician.

It is important that there be a continuity in the worker's occupational health record and that the employer be required to store an employee's record even after the termination of his employment.

The rapid development of medical knowledge and new laboratory technology prompts the recommendation that at least every three years NIOSH convene an advisory committee of qualified medical experts to review the continuing applicability of the clinical laboratory tests, examination procedures, and X-rays which are the established minimum requirements under the OSHA standard. Acting upon their

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evaluation and suggestions, the Department of Labor would then revise the medical surveillance requirements. This will permit the use of the best available newly developed techniques, as well as protect the worker from tests which are proven to be no longer of diagnostic value.

It is anticipated that data gathered from the rapid implementation of this examination system, coupled with information arriving from ongoing environmental monitoring and epidemiological clinical studies, will help establish -- and animal studies -- will help establish the basis for prevention and control of these occupational health hazards.

JUDGE MYATT: All right. Now we'll hear from the representative of the Solicitor's Office.

MS. GHOLSTON: I have a question for Mr. Mancuso -- excuse me, Dr. Mancuso.

In the beginning of your testimony you mentioned inhalation and ingestion tests, but I believe you distinguished between them by saying that one was more similar to the conditions of the worker --

DR. MANCUSO: Inhalation is. I was pleased to see in the experiments which are now underway and the studies which were done by Dr. Viola that they did use inhalation experiments, but if you will study the experimental literature, however, it's amazing, really, the majority -- the greater percentage of the majority purely for economic

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reasons, the animals were rarely tested by ingestion, feeding them, and also by injection. Inhalation experiments, of course, are much more costly, but the ingestion and the injection experiments really do not parallel what the worker does. His primary mode of exposure is inhalation, but also by contact through absorption through the skin.

MS. GHOLSTON: Thank you.

JUDGE MYATT: Anything further?

MS. GHOLSTON: Nothing.

JUDGE MYATT: Yes, sir?

MR. CONNOLLY: I'd like to address this question to the entire panel -- I'm Walter Connolly with the Firestone Rubber Company.

Mr. Mazzocchi, earlier this morning, did not give any indication that there were any deaths that resulted in the same type of problem that B. F. Goodrich has come in contact with. Does anyone on the panel know of any other deaths that we are not familiar with in the industry that would relate to this particular problem?

MR. SAMUELS: We are now investigating some reports that are, so far, unconfirmed and Dr. Anderson has, in addition to that --

DR. ANDERSON: I believe Dr. Selikoff mentioned this morning that he had been given a personal communication from some doctors in England that they do have one additional

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case of angiosarcoma.

MR. CONNOLLY: To your knowledge, there are none in the United States?

DR. ANDERSON: None yet.

MR. CONNOLLY: I presume that the unions involved, not only OCAW, but the AFL-CIO unions, would have come in contact with such a problem through workmen's compensation cases.

MR. SAMUELS: First of all, we have not yet completely studied the population risk, so the fact that we have not yet had brought to our attention cases doesn't mean anything. The state of workmen's compensation, as you, I'm sure, know is such that what you don't reveal or have revealed through that process is also meaningless for purposes of medical investigation.

MR. BELICZKY: I'd like to respond to that question. First of all, I think it's a loaded question -- and I know why as well as you do.

Secondly, as far as workmen's compensation claims at the present time related to the production of the polyvinyl chloride resin and the relationship to either liver disease or to angiosarcoma of the liver probably hasn't entered the minds of too many people because it hasn't been published as such. So, therefore, any basis for claims or comments or getting conclusions regarding workmen's

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compensation is certainly not the direction to go at the present time.

MR. CONNOLLY: I have one final question --

DR. MANCUSO: Can I add to that question? It's a very important question because as far as I'm concerned it should be put to rest. Under no circumstances should anyone use the workmen's compensation claims as an index of what in the world happened to the industrial population. In the first place, the worker doesn't even recognize an occupational disease when he sees one. In the second place, the general practitioner doesn't recognize it. Consequently, it doesn't come to a compensation claim. So I would say, even in this particular case, which is very difficult, it would be very foolish and unwise to use that as an index.

MR. CONNOLLY: One final question: as Mr. Mazzocchi correctly prognosticated, corporations have testified that to their knowledge there are no deaths other than the ones at the B. F. Goodrich plant. Can any conclusions be drawn from the fact that Firestone's facility has utilized this material over the past 27 years and no deaths have occurred comparable to the type that B. F. Goodrich has come in contact with that might be relevant to this hearing?

DR. MANCUSO: You were saying you have a plant that's been in operation for 26 years?

MR. CONNOLLY: Twenty-seven years utilizing this

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material.

DR. MANCUSO: The question would relate to how well the medical records were kept and what kind of medical surveillance was done.

I'd like to ask you a specific question: one is, what kind of continuous environmental or medical surveillance system exists in Firestone, and how do you trace all the employees, and do you know or does your company know what happens to each individual after he is separated from employment and what his health effects or what diseases subsequently occur? If you do not know and you have no surveillance system for that purpose, then there's no way for you to determine that no deaths have occurred due to this particular disease.

MR. CONNOLLY: I think Mr. Beliczky can attest to the study that we have at the North Carolina Medical School. However, since we're not submitting testimony today, I just asked: are there any conclusions you can draw from the fact that no deaths have occurred at Firestone that we know of --

MR. BELICZKY: Since you already mentioned my name, and you mentioned the URW, and you mentioned an occupational health program, any conclusions you reach are very, very premature. It's unfortunate that you have to talk about deaths, because nothing can be done about the poor souls who have passed away. But I can inform you now that I know of

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people in your plant that have serious liver disease which could eventually lead to death, so I wouldn't embellish comments, as you have made, to say that you do not have a problem, and that the problem that you do not have is related to the fact that you don't have deaths.

So, again, I would be awfully careful when we talk about the people who work in your plant and their exposure, because I've been to that plant. I know the concentration of some of the exposures in the plant. I know that some of the people have high concentrations, high enough that they became narcotized during and after their exposure.

So, again, I don't like to have anyone base any judgment on the fact that you don't have a problem because you haven't had a death at the plant directly related to angiosarcoma of the liver. I'm sure that death certificates have not been properly filled out to date.

I don't want to involve the University of North Carolina at this point.

MR. CONNOLLY: I think Firestone is not overly enamoured by any of the results that have emanated from this hearing, but we would assume --

JUDGE MYATT: Mr. Connolly, I'm going to cut you off on that. That is not pertinent to what we're doing. It should be fact-finding, and now you're interjecting Firestone's situation, but that isn't helping us in this

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fact-finding situation. You can discuss that with Mr. Beliczky at another time.

MR. CONNOLLY: We're willing to present evidence at this hearing, this fact-finding hearing, relative to the points that he mentioned --

JUDGE MYATT: Firestone is listed on here.

MR. CONNOLLY: I'm talking about later. We're not going to testify today.

I'm asking whether or not the URW or the AFL-CIO has testimony they're planning to present relative to the Firestone situation.

MR. BELICZKY: Not at this time. If I would have, I would have presented it.

JUDGE MYATT: All right. Are there any other questions of these gentlemen?

Gentlemen, thank you.

Dr. Jeager, would you have time enough, if we took you out of turn, to give your oral presentation?

All right. We're going to make a modification here in an effort to accommodate Prof. Jaeger, who has a flight scheduled out of National at 5:15. He says he has a brief presentation that he feels he would like to give, and then we will get to Dr. V. K. Rowe.

PROF. JAEGER: My name is Rudolph Jaeger. I live in Westwood, Massachusetts. I hold a doctorate, a Doctor of

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Philosophy in biochemical toxicology. I am a member of the faculty of the Harvard School of Public Health.

My statement is prompted by the earlier ruling that questioners -- questions may only be asked by participants or their representatives.

I represent no one but myself. I am an inhalation toxicologist and a consumer of plastic products. My deposition which I have given to Ms. Goodell relates to the evaporation of a plasticizer from heated polyvinyl chloride meat wrapping film.

While this problem is currently the subject of a NIOSH study, the cause of "meat wrappers' asthma" is not yet known.

Angiosarcoma in PVC polymerization workers is being studied as a result of the association of this occupation with the death of four workers and the apparent preillness conditions of four more persons. While there appears to be little doubt that vinyl chloride monomer is a carcinogen to rats, the human carcinogenic potential of this substance or any other substance should not have to be evaluated in man.

The predictive science of experimental toxicology has been with us for some time. It is sad that humans had to prove Dr. Viola to be correct.

While I must caution myself about the danger

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implicit in self-serving statements, I must address myself to three areas. First, the possibility exists that polyvinyl chloride resin or compounds or similar materials may contain an agent admitted to be carcinogenic; second, the possibility exists that polyvinyl chloride or propolymers of vinyl chloride by virtue of their use may release substances known to be carcinogenic; third, the possibility that reactive polymeric monomers may, like polyvinyl chloride, produce cancer in workers exposed to such agents should be considered.

It is my contention that we must exonerate of carcinogenic potential all finished polyvinyl chloride materials available to the consumer. This must be done immediately and with a zeal consistent with our concern for the public health. All workers at each stage of PVC processing must be similarly protected.

With respect to the possibility that PVC use or disposal may result in the release of a carcinogen, research in this area should be intensified. The possible pyrolytic evolution of vinyl chloride from PVC materials must be determined. Examples of this are large-scale municipal incineration of plastics and the cutting of polyvinyl chloride meat wrapping film with an electrically heated hot wire.

Lastly, the possible carcinogenic hazard of other

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plastic monomers cannot be laid aside. For instance, vinylidene chloride is a more potent pathotoxin than vinyl chloride, both acutely and chronically. It is used in the manufacture of vinyl chloride-vinylidene chloride propolymers. However, there does not currently exist, to my knowledge, a published lawful TLV for this agent, much less an assessment of its carcinogenicity.

In conclusion, I don't wish to be identified as an alarmist; rather, I would close on the words of a famous scientist who was asked his thoughts when he observed an interesting phenomenon, "I didn't think, I investigated."

JUDGE MYATT: Are there any questions of Prof. Jeager?

Thank you, sir.

All right, Dr. Rowe, if you will.

DR. V. K. ROWE

DR. ROWE: Your Honor, I am V. K. Rowe of the Dow Chemical Company. Currently I am a research scientist concerned with the over-all, broad aspects of Dow's health and environmental research. Prior to being named to this post in late 1973, I was director of our toxicology laboratory and industrial hygiene research.

I shall summarize for the record the following: (1) scope of the vinyl chloride industry; (2) the basic toxicological information; (3) the health parameters studied

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in vinyl chloride workers; (4) our industrial hygiene experience in all of our plants; (5) analytical and monitoring procedures; (6) items found effective in maintaining safe operations; and finally, (7), some suggestions for the future.

I believe it will be apparent that the industry learning curve for vinyl chloride is advancing.

1. The scope of the vinyl chloride industry. Dow Chemical USA began producing vinyl chloride monomer on a very limited scale in Midland, Michigan, in 1939 and production remained relatively low throughout the war period. In 1946 production of vinyl chloride began in our Texas division at Freeport, Texas. Capacity was expanded at this location through 1956.

In 1958 our second monomer plant was brought on stream at Plaquemine, Louisiana, and a third was added in 1969 at our Oyster Creek Division.

In 1952 Dow was one of seven U. S. producers of vinyl chloride monomer as reported in the first U. S. Tariff Commission report on vinyl chloride. Today there are ten producers of vinyl chloride monomer, Dow being one of the large merchant suppliers. In addition to producing monomer, Dow operates a small polymerization plant.

The quantity of vinyl chloride produced in the U. S. has grown quite rapidly. Production increased from

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approximately 321 million pounds in 1952 to a billion pounds in 1960, two billion in 1965, four billion in 1970, to an estimated 5.3 billion in 1973. This monomer growth rate illustrates the high demand for the plastics produced from vinyl chloride -- and I have a table which I shall not read into the record giving you this kind of data. It will be in my submission.

Vinyl chloride is the second largest volume monomer produced in the United States. There are two commercial processes, which have been discussed and in the interest of brevity since they are already read into the record, I will avoid discussing them.

However, I would like to point out that the principal process used by Dow is the one which involves the thermal dehydrohalogenation of ethylene dichloride.

Vinyl chloride is one of the purest organic compounds produced commercially. A typical analysis of vinyl chloride produced by Dow shows less than 20 parts per million of total organic impurities. These trace impurities are acetylene, 1,3-butadiene, methyl chloride, and vinyl acetylene.

Nearly all the vinyl chloride monomer shipped by Dow is uninhibited; however, a small amount is inhibited with 25 to 75 parts per million phenol. The phenol is subsequently removed by the use of a caustic wash.

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I wish to emphasize the diversity of plant and process operations in producing and using vinyl chloride. Commercial plants for producing vinyl chloride range in capacity from modest size up to several hundred million pounds. Some of these plants are new, some are fifteen to twenty years old.

There are three distinctly different polymerization processes which have also been described previously, suspension, emulsion, and bulk processes.

I will cite many of our plant practices, but strongly recommend that OSHA recognize the diversity of monomer manufacturing and polymerization operations when they consider the establishment of a workplace standard or standards. Other producers and processors will have different types of jobs, different equipment, and different engineering, monitoring, and procedural approaches. Dow strongly believes that a standard should emphasize in objective terms what is to be accomplished so that a number of engineering and procedural approaches may be employed under the standard depending on the particular plant situation.

The toxicology of vinyl chloride. Earliest studies on vinyl chloride were limited to acute exposures, as typical of the toxicity studies of the day. These observations led to its consideration even as a surgical anesthetic. Generally, these studies showed vinyl chloride to be low in acute toxicity, to be anesthetic in action, and

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to have little capacity to cause liver injury from exposures of a few hours. Mastromateo, et al., 1960, and Lester, et al., 1963, reported on acute exposures of animals and humans.

With respect to humans, they reported very little effect until exposure concentrations approached 10,000 parts per million when dizziness was reported after five minutes of exposure. In animal work, no deaths occurred in rats exposed for a half to two hours to 100,000 parts per million and exposures to 150,000 to 200,000 parts per million for a half to two hours caused anesthetic deaths, as did higher concentrations for shorter periods of time.

I have also a table entitled "Acute Inhalation of Toxicity for Vinyl Chloride," which I will not attempt to read in as it is a part of the record.

In the exposures to high levels of animals, lung congestion and edema were present after 42 minutes of exposure to 150,000 parts per million, but according to Lester, Greenberg liver and kidney injury were not apparent.

Since 1962, numerous non-U. S. articles on vinyl chloride have appeared, particularly in the Russian literature. Several of these studies involved acute exposures and the observed effects were generally subtle changes. I am well-aware, however, that there are reports that indicate low concentrations having caused a variety of changes. I would like to add here that these changes need

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to be evaluated, the report needs to be evaluated because there is no data that I have to permit me to evaluate the quality of the work that was done.

The chronic toxicity of vinyl chloride has been studied by several investigators. Torkelson, Oyen, and Rowe, 1961, reported their results, and these again have been read into the record several times today, so I will only briefly comment that we had very minimal effects -- slight effects at 200 parts per million, very little at 100 -- as a matter of fact, it consisted of slight liver and weight increases in rats, with no effect on dogs, guinea pigs or rabbits exposed six months, seven hours a day, to 100 parts per million, and we detected no changes whatsoever in any of the four species after six months of exposure to 50 parts per million.

We concluded that the exposure should be limited to less than 100 parts per million with a time-weighted average not to exceed 50 parts per million.

And again, as pointed out previously, Lester, Greenberg, and Adams took exception to the conclusions of Torkelson, et al., and recommended 500 as a time-weighted average exposure. They cited for their reasons one table entitled "Result of Repeated Seven-Hour Exposure of Male and Female Rats to Vinyl Chloride." They exposed these animals to 50,000 parts per million for 19 days and observed in-

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coordination, normal hematology, increase liver weight, normal gross pathology, slight liver histopathology. And at 20,000 parts per million for 90 days they had normal hematology, increased liver weight, normal gross pathology, slight liver histopathology, which was considered to be within normal limits.

Because of these conflicting reports, the TLV Committee of the ACGIH in 1963 chose to change their TLV from 500 ppm as a maximum time-weighted average for industrial exposure to 500 ppm as a ceiling value.

Because of the report of acroosteolysis in humans, Prof. Viola of the Regina Eleva Institute for Cancer Research in Rome, Italy, attempted to produce the disease in animals, and the results of his work have also been read in, so I won't take the time to do it.

The report by Viola, et al., is apparently the earliest and only publication in which carcinogenic activity has been ascribed to vinyl chloride -- that is, up until the report we heard this morning. Although there are possible deficiencies in Viola's study, such as the quality of the vinyl chloride sample used in the study, the presence of food and bedding in the exposure chamber, and the excessive exposure concentration used, the report nevertheless gave rise to serious concern and resulted in the initiation of additional animal studies and epidemiological studies which

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are currently underway and which were described by the Manufacturing Chemists Association in testimony this morning.

In summary, we could say that the acute effects from short-term exposure occur at high environmental concentrations; chronic or long-term effects occur at moderate concentrations. The most sensitive toxicological response observed to date is the effect upon the liver. The central nervous system effect in human beings is related to concentration, and here, again, the tests involved will dictate what that level is.

We are submitting in triplicate -- we are submitting triplicate copies of the toxicological literature on vinyl chloride for OSHA reference, and this is Appendix 1 of my testimony which you have.

Now to the health parameters studied in our workers. Dow is cooperating with the Manufacturing Chemists Association which has retained Tabershaw-Cooper Associates to do an industry-wide study of the health of workers exposed to vinyl chloride. Currently, we have approximately 320 employees in vinyl chloride operations. We have submitted to Tabershaw-Cooper employee records covering 916 personnel who have been involved in vinyl chloride operations over the years. This study is incomplete and will be reported at the appropriate time. However, we can make the following preliminary comments on the health parameters of Dow vinyl chloride

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workers.

Preliminary data from Dow manufacturing units reveal no deaths due to cancer of the liver.

Preliminary data likewise reveal no deaths due to cirrhosis of the liver, and we have had no cases of acro-osteolysis.

At the present time, we are unaware of any living employee who has been exposed to vinyl chloride suffering from cancer of the liver. Like[illegible] we know of no case of cirrhosis of the liver in employees exposed to vinyl chloride. However, this information is incomplete and it is being subjected at the present time to critical research.

[illegible] Preliminary studies in two major manufacturing locations with the longest history of vinyl chloride production reveal no increase in abnormal liver function tests above that expected in a similar unexposed population.

C. G. Kramer, M. D., and J. E. Mutchler published in the American Industrial Hygiene Association Journal in 1972 a study of vinyl chloride workers in one location. Findings suggest that repeated exposure to vinyl chloride at time-weighted average levels of 300 parts per million or above for a working lifetime together with a very low level of vinylidene chloride may result in slight changes in certain physiological and clinical laboratory parameters. The possibility of some impairment of liver function must be

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considered even though no overt clinical disease was evident in any of the individuals studied. This study showed a definite dose-response correlation between the intensity of exposure and the deviation from normal values.

We will continue to cooperate with the Manufacturing Chemists Association in the Tabershaw-Cooper studies. Additional in-depth studies will be continued within the various manufacturing units of the company and will be reported upon when completed.

Industrial hygiene measurement of vinyl chloride in workplace air. Dow has monitored the workplace environment by a variety of techniques, including: (A) continuous monitoring of representative or selected workplace areas by a combustion-conductivity analyzer; (B) "grab" samples of workplace air collected in impervious plastic bags or activated carbon "slugs"; analysis of such samples is now by gas chromatography, but years ago analysis was by determination of total chloride or by infrared spectroscopy. (C) personnel monitors based on absorption on activated carbon slugs, followed by gas chromatographic analysis.

Our monomer plant No. 1 started operation in 1946. Historically, spot sampling was conducted. Loading of tank cars, collection of samples for product assay and distillation operations were the only tasks which needed attention in the early operation of this plant.

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In 1972 an extensive industrial hygiene survey was conducted. Multiple grab samples were collected in impervious plastic bags and analyzed by gas chromatography. The four control operator classifications had time-weighted average values between .2 and 1.3 parts per million. Maintenance employees had time-weighted average values of 1.7 parts per million and the supervisory employees had a TWA of 1.3 parts per million. The loading operations had a TWA value of 45 parts per million and the laboratory employees who collect samples from storage tanks had a TWA of 14 parts per million.

Personnel monitoring is presently being carried out on a systematic and periodic basis in this production unit. In 1973 all TWA values were below 10 parts per million except for the laboratory employees who had TWA exposures of up to 30 parts per million, a level well below our industrial hygiene guideline of 50 parts per million.

Monomer Plant No. 2 started operation in 1958. Limited surveys were conducted in 1955 and revealed time-weighted averages ranging from 9 to 60 parts per million. An in-depth survey was carried out in 1973. All TWA values were below ten except for the laboratory employees. Their values were between ten and fifteen parts per million.

Monomer Plant 3 began operation in 1969. In a 1973 personnel monitoring study, TWA values ranged from less than one part per million to ten parts per million.

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Our Polymer Plant No. 1 was operated from 1946 to 1972. Between 1950 and 1959 several industrial hygiene surveys were conducted. A number of job classifications, polymerizer operators, drier operators, monomer still operators, and monomer transfer operators, had workplace environmental levels ranging from 50 to 385 parts per million vinyl chloride. After installation of a continuous analyzer for the workplace air in 1959, improvements were achieved. Vinyl chloride TWA values ranged from 25 to 85 during the period of 1960 to 1967.

Our present polymerization plant, Polymer Plant No. 2, began operation in 1953. Historically the TWA values have been decreased over this period of time. In the early history, TWA values of 105 to 240 parts per million were observed. During '73 similar values for vinyl chloride in the air were in the one to twenty-five parts per million range.

We emphasize that there is some variation in TWA values from day to day for a given type of operation. For example, operators involved in pumping reactors showed values ranging from 1 to 34 parts per million. Similarly, three operators involved in loading operations had TWA values ranging from 8 to 31 parts per million. We encourage recognition that such variations will occur in normal day to day operations involving transfer of monomer.

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METROPOLITAN REPORTING SERVICE, INC.

We are including reports on a number of our industrial hygiene monitoring studies as written supplements to this statement and they are labeled Appendix 2.

In summary, the industrial hygiene data shows that levels of exposure below 50 parts per million are obtainable in both producer and user plants of vinyl chloride. It must be noted, however, that with the older plants the achievement of such goals may be difficult and in all probability will require modifications that will take time to accomplish.

Safety in the vinyl chloride industry. The operation of a safe plant involving the handling of toxic, hazardous materials revolves around a number of factors:

1. Establishment of safe, practical, allowable environmental levels.

2. Implementing appropriate engineering and operating procedures to achieve or better these levels.

3. Providing analytical monitoring capability to insure the environment is maintained below the established levels and to detect excursions above such levels.

4. Initiating appropriate corrective action when breakdowns occur and guideline environmental levels are exceeded.

Developing and supporting an appropriate medical surveillance program.

Dow has a safety philosophy that the safety of our

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employees, our customers, and our neighbors is of prime and utmost importance. This safety philosophy permeates our operations. To achieve our general safety goals for vinyl chloride operations and to achieve a goal that industrial exposure to vinyl chloride should be kept below 50 ppm on a time-weighted average, we have implemented the following design and engineering principles for vinyl chloride operations:

1. Processing systems are closed with no open vessel operation.

Current buildings where vinyl chloride is manufactured or polymerized are open to the atmosphere or have ventilation to minimize concentration build-ups.

3. Engineering design emphasizes reasonable process automation and reasonable remote operation in order to minimize personnel exposure.

Vent exhaust systems are selectively located to minimize the possibility of personnel exposure.

And the number and quantity of samples for control analyses are minimized.

Careful application of the above principles has led essentially to the attainment of our goal of TWA values of less than 50 parts per million in our operations.

We believe that good operating procedure must be tailored to each specific plant, that plant size and the

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nature of the process and the plant location all will influence the exact procedures to be carried out. I will mention a few of the more important operating procedures and techniques involved in one of our monomer production plants to illustrate the complexity of good plant operation.

1. Employees are familiarized with emergency procedures and signals. For example, wind directional signals, horn emergency calls, and evacuation routes.

2. Collection of analytical samples of vinyl chloride from storage tanks involves a closed-loop sampling system in order to return vinyl chloride to the process rather than venting vapor in the workplace environment. Laboratory samples of vinyl chloride are handled in hoods and sample cylinders are grounded when discharged. On-line gas chromatography is being used extensively to monitor product purity and process operation. This has reduced markedly the number of manual sample collections required, and this has occurred over the last few years.

Specially designed vapor equalizing lines connected back to the storage tank are employed in the loading of tank cars.

4. Environmental monitoring of air is being conducted by a number of techniques. Gas detector alarms are located throughout the plant at a number of strategic locations to warn of any flammable concentrations. Portable

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detector instruments are available for checking plant areas or process equipment prior to non-routine operations and procedures. Air quality surveys were conducted in Monomer Plant No. 1 in 1971 and in the first quarter of 1974. A continuous analyzer system for twelve strategic locations in the plant will be installed. This will provide continous background information and provide instantaneous signals for any unusually high concentrations that might occur due to leaks, spills or other non-routine situations.

In our polymerization operations we have not had problems of worker illness from the cleaning of polymerization vessels. We utilize high pressure water jets after each polymerization reaction to prevent polymer build-up. Our emulsion polymerization kettles require manual clean-out every two or three months. After water cleaning of the vessel, all lines are blanked to prevent any material from entering the vessel and the atmosphere is tested for oxygen supply and a continuous vinyl chloride monitoring probe is put into the vessel. Concentrations must be below 50 parts per million prior to vessel entry. Air purge is maintained on the vessel during the cleaning operation.

Analytical methodology. Four methods are available for environmental monitoring of air for the presence of vinyl chloride: (1) conbustion-conductivity, gas chromatography, infrared spectrophotometry, and flame ionization

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spectrophotometry.

Gas chromatography is very specific, but requires about ten minutes per sample. Flame ionization detectors have no specificity-responding to all carbon-carbon or carbon-hydrogen bonds, but are portable and the measurement is instantaneous. The combustion-conductivity method responds to any material which burns to produce ions. It responds rapidly. Infrared analyzers are very specific, respond quickly, and are portable. All of these techniques have adequate sensitivity, detecting concentrations of as low as one part per million.

Personnel monitoring is achieved through the use of absorption tubes filled with activated carbon. The absorbed chlorinated hydrocarbons are determined by gas chromatography after thermal release or extraction by carbon disulfide.

At Dow most of our environmental monitoring has been with combustion-conductivity analyzers. We have used these analyzers for continuous monitoring since 1959 with excellent results.

And now for recommendations for government-industry action.

Dow urges OSHA to recognize the voluntary industry action to lower the levels of exposure to vinyl chloride and the leaf role of industry in obtaining data on the vinyl chloride problem.

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Dow believes the industry recognizes the need to maintain environmental levels below the OSHA standard of 500 ppm and even below the ACGIH recommendation of 200 ppm.

Dow believes that it is industry's and government's responsibility to inform all employees or persons working with vinyl chloride about its hazards and to develop and implement training programs to help prevent overexposure and insure proper reaction in emergency situations. We believe informed employees will cooperate in eliminating over-exposure and suggest methods for improvement.

Based upon the medical and toxicological data available to us at this time, Dow believes that an eight-hour TWA of 50 ppm is a satisfactory environmental standard for vinyl chloride.

Dow is supporting and actively cooperating in long-term inhalation, metabolism, and epidemiological studies in order to obtain the most precise data possible relating to the potential for occupational health assessment.

(A) We will strongly support industry-government evaluation of the data as it becomes available.

Results of the epidemiological survey of vinyl chloride workers initiated about a year ago by MCA via contract with Tabershaw-Cooper will be available in the near future. It seems reasonable to expect that these results will provide additional and substantive basis for rule-making.

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Dow believes rule-making should not be based on conditions that existed in the past but should be based on conditions as they exist now. Based on NIOSH activity and on widespread voluntary actions by industry, we believe there is no need for a temporary emergency standard. Realistically, we believe a temporary emergency standard would result in polarization rather than constructive definition of areas of concern and constructive problem solving.

We believe most users/producers of vinyl chloride have or will soon have the capability to maintain an eight-hour time-weighted average of 50 parts per million or below. Therefore, we suggest that steps be taken in order to develop the standard in a reasonable way.

In order to asses the state and magnitude of the problem, we suggest that each producer/user of vinyl chloride complete an industrial hygiene survey of his operations and a medical survey of vinyl chloride workers within three months and report the results of each survey to NIOSH and OSHA.

If the survey reveals TWA's in excess of 50 ppm, the manufacturer or processor should immediately take steps to reduce exposure by operational and/or engineering changes and require the use of appropriate respiratory protection by his employees likely to be exposed to such levels.

If the medical surveillance program indicates

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abnormalities that could be attributed to excessive exposure to vinyl chloride or a condition that could reasonably be expected to be aggravated by continued work with vinyl chloride, that person might well be removed to another job not involving such exposure. We recommend NIOSH assistance in defining the priority of health parameters for this study.

Dow supports OSHA's establishment of a permanent health standard for vinyl chloride by regular rule-making procedures.

And we recommend that the standard state what should be accomplished, leaving the "how-to-achieve compliance" to individual plant implementation.

Thank you, sir.

JUDGE MYATT: Thank you, Doctor.

We are going to mark as Exhibit 15(a) Dr. Rowe's statement, "Toxicological Data and Industrial Experience with Vinyl Chloride," 15(b) Appendix No. 1, the published references to the biological effects of vinyl chloride, and 15(c), Appendix No. 2, the industrial hygiene surveys involving vinyl chloride.

(Whereupon, Exhibits Nos. 15(a), 15(b), and 15(c) were marked for identification and were received in evidence.)

JUDGE MYATT: We are also going to mark, Madam Reporter, as Exhibit 14 an article by Dr. Jaeger, which I

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JUDGE MYATT: Yes, Mr. Beliczky.

MR. BELICZKY: I just wonder if I could ask V. K. is he has any idea of how much VC is in the polymer after the polymerization reaction, maybe put into bags, barrels, shipped, put into boxcars.

DR. ROWE: Lou, I don't know. I don't know whether the information is available or not. I haven't looked into this. However, I am certain that the amount that's going to be there will depend upon the intensity of the degassing process in the final steps of polymerization, and I'm sure that there are many variations to this and I can't tell you what ours runs, and I don't know what other people's do either.

MR. BELICZKY: We heard Dr. Maltoni this morning talk about certain kinds of carcinogenic responses in animals to various concentration exposures to vinyl chloride, and I think he did mention that he did find some carcinogenic response in 100 parts per million. In relating this -- this is an animal, and we are concerned about human beings. What degree of surety do you have or confidence in a level of 50 parts per million?

DR. ROWE: I was not aware that Prof. Maltoni mentioned any positive effect at 100. I could stand corrected. I'm not sure that I understood everything he said. But I don't believe -- I didn't hear that and I didn't see it on

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the tables.

MR. BELICZKY: It was either 100 or 200. I'm not quite sure.

DR. ROWE: 250, I think he did.

JUDGE MYATT: Yes?

MR. SAMUELS: Dr. Rowe, first let me say that if your other colleagues in the industry had followed your advice in 1961 following the publication of your paper, we perhaps would not be faced with this crisis. Nevertheless, you were a member of the Standards Advisory Committee on Carcinogens, and I wonder why you choose to handle this carcinogen any differently than the carcinogens approach as described by the Committee, namely, the purpose of this standard -- and I'm quoting from the Committee report -- "The purpose of this standard is to prevent any worker contact or exposure to any of the listed carcinogens" -- it could be vinyl chloride or the process of polymerization -- as detected by the most sensible, feasible sampling and analytical methods available. The vote on that was fourteen to nothing.

DR. ROWE: Well, Sheldon, I don't want to get into all the arguments and the discussions that went on at the Advisory Committee on Carcinogens, but there was a matter of timing when that was developed and we were coming back to discuss some other matters later on as to how that should be implemented, and we were not able to do that at the end, so



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that stands as a part of the record, a part that I would not concur to completely.

I think we want to reduce these, but I do feel that there is a reasonable level -- and you asked me about why I feel the way I do. I feel that from my knowledge of some of the things that have gone on there must have been a rather severe exposure, very severe exposure, of people many years ago that we are seeing the results of today.

Our experience, which is just as long, but under control conditions, we have not seen this. Now, we have looked at almost everybody we can find. We have a few people who yet -- we're going to have to have some help through Social Security numbers or other means to find them. We have all the people who are retired; we know all those. We have our own people; we know the people who have died. There are a few who have worked a very short time and quit or left for other reasons, and those are the ones that we don't have. So I can't be completely conclusive in my remarks that we have not had any, but I don't believe so.

MR. SAMUELS: Can I ask this further question, then? I will admit to the theoretical possibility that 50 parts per million or some other parts per million, some other level, some other dose relationship might be safe, but until that's shown and proven, do you think it's prudent to take the risk with the lives of thousands of workers?

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DR. ROWE: I don't believe that there is that great a risk, if we control our concentration during this interim period during which we're developing, I think, very significant data, and that's why I feel that we ought to go ahead in a practical way because it would be absolutely catastrophic to the whole affair if we were to have to go down to none. It would be essentially impossible continuing operations --

MR. SAMUELS: We're not talking about none. We're talking about methods that are already feasible for detection and we've been told by the industry that your methods of analysis, using the shelf instruments, instruments that can be purchased off the shelf of vendors, will enable you to measure concentrations of vinyl chloride in the range of ten to thirty parts per million. So we're not talking about none. We're talking about your doing what's feasible in terms of measurement.

DR. ROWE: I thought that's what I was trying to recommend.

MR. SAMUELS: Well, you recommended fifty.

DR. ROWE: Anything below that --

MR. SAMUELS: We're saying it should be tied not to the assumption of the TLV, which has not been demonstrated -- in fact, it has not been demonstrated -- but , rather, to the method of measurement, and if some instrument manufacturer develops a more sensitive instrument, then we expect you to

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achieve that level of detectability.

DR. ROWE: I think that is quite an ideal situation because the challenge of any analytical -- good analytical man in instrumentation can extend that by orders of magnitude with just a matter of a few months or a year's research. We've seen this when it is absolutely necessary to do so. So that's kind of -- you run out of space, Mr. Samuels.

JUDGE MYATT: Yes, ma'am?

MS. HRICKO: Dr. Rowe, you said that Dow has very carefully controlled the levels of vinyl chloride at these various plants since they started their operations, yet you stated that Plant 2 started up in 1958 and you did a spot survey in 1965 at a level showing that they were all under 60; then you did a more in-depth survey in 1973 showing that all values except for lab personnel were under ten. I can only assume from the way you presented the data that there was not continuous monitoring from 1958 to 1973. If there wasn't and there were only these surveys done in those two years, how can you assume that the levels of vinyl chloride did not have great excursions during those years?

DR. ROWE: I said what I said because I can't produce data to demonstrate what happened during those years. I know what happened, but I don't have data to prove it.

MS. HRICKO: Was there continuous monitoring?

DR. ROWE: The monitoring was done and the people

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in the plant -- this is recorded right in the plant and there are such volumes of paper that are generated on a day-to-day basis that if everything was right, they threw them in the waste can.

MS. HRICKO: So there was continuous monitoring. You just happened to pick out '65 and '73 as examples?

DR. ROWE: I did pick out some examples, yes. These are ones that we have records for and documentation in our files.

MR. BELICZKY: Of the methods that you described for monitoring, which of the methods could go down to one part per million?

DR. ROWE: I think any one of them can.

MR. BELICZKY: Can the flame ionization procedure distinguish, let's say, between vinyl chloride and vinylidene chloride?

DR. ROWE: I'm not an analytical man or a spectroscopist here, Lou. I think it can. I think it's quite highly specific.

The thermal conductivity -- the combustion-conductivity unit will not, of course.

MR. BELICZKY: Since you've never thought of really going beyond -- let's say below 50 parts per million. I'm now thinking of one part per million. Do you conceive of any real technical difficulty in going down to a tenth of a part

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per million if one part per million is easily achievable -- in instrumentation.

DR. ROWE: In instrumentation? No, that's no problem.

JUDGE MYATT: All right. Are there any further questions of Dr. Rowe?

Thank you very much, Dr. Rowe.

We have remaining Mr. Herbert Carver of Dove Packaging Systems Division of Franklin Electric and Dr. Robert Brookman, Manager of Research and Development of Firestone.

Is Mr. Carver here? Step up, please, sir.

What I propose to do is to continue on. I know it's after 5:00 -- it's only five after. I'm assuming that with only two individuals left to make a presentation that we can conclude this by 6 o'clock, if you'll bear with us.

Mr. Carver.

HERBERT K. CARVER, JR.

MR. CARVER: My name is Herbert K. Carver, Jr. I am employed as a design engineer with Dove Packaging Systems Division of Franklin Electric, headquartered in Fallsington, Pennsylvania, with a mailing address of Box 666, Levittown, Pennsylvania, 19058.

Dove manufactures packaging, weighing, and labeling equipment primarily for exposure in the supermarket

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industry.

One of the long-established product lines is console and table-top hand wrapping stations used by supermarket personnel to manually overwrap meat and produce. The overwrap packaging material is roll stock plastic films such as polyethylene and polyvinyl chloride.

Briefly, the Dove manual overwrap operation includes wrapping the film around a tray-held product, thermally severing the film web, heat sealing the bottom of the package, and, in the case of shrink films, thermally shrinking the film around the package.

Several years ago we started a project to develop a means to reduce the visible quantity of "smoke" released in the high-temperature, hot wire thermal severing of the film. This led to the issuance of a patent to us which basically involves the regulation of the severing wire's temperature below the combustion point of the film. This way the film is softened and then severed mechanically by the force exerted by the operator who is performing the wrapping.

To us, as chemical laymen, the reduction of visible smoke indicated a step in the right direction. Our intuitive feeling on this point seems somewhat justified based on the results reported in the Health Hazard Evaluation Determination, Report 72-53, issued in September 1973 by the U. S. Department of Health, Education and Welfare, Hazard

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Evaluation Services Branch of NIOSH, Cincinnati, Ohio. This report generated from a request of an authorized representative of the supermarket meat wrapping employees for an investigation regarding employee exposures to the potentially toxic substances emitted from thermal decomposition of polyvinyl chloride packaging films.

Following are some excerpts from this report which led us to this belief: "...the production of both HCl and airborne particulate increase with increasing wire temperature ...machines with low temperature cutoff wires are to be preferred..."

Further, as mentioned in the subject NIOSH study, there are differences of opinion on the exact nature of the emissions and inconclusive results concerning the effects of these emissions on the operator performing the wrapping. However, it would seem that a temperature-controlled film separation technique, as recommended in the NIOSH study, is a step in the right direction.

The use of such a technique would maximize the utilization of established wrapping methods and equipment. Also, it should minimize the wrapping speed reduction and film waste indicated with other cutting techniques, such as knives. In these days of reported declining supermarket meat room profits and petrochemical shortages, such points must be seriously considered.

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Being a supplier of hand-wrapping equipment, the Dove Packagaing Systems Division is continually concerned with providing acceptable and efficient equipment to the super-market industry. For some time Dove hand-wrap stations have been equipped with a controlled low temperature thermal cutoff mechanism and it is our goal to equip all remaining newly built models with a similar mechanism.

We offer whatever help we can to resolve this question.

Further, if it is determined that the thermal products of "hot wire" cutting of PVC film are potential health hazards, we offer the use of our low temperature technique and/or equipment to OSHA and NIOSH as a baseline for the development of a specific standard.

In closing, to all participants in this hearing, as well as those not in attendance today, please be advised and assured that we have a serious interest in the resolution of this concern.

For the Dove Packaging Systems Division of Franklin Electric, I submit this statement for the OSHA record.

JUDGE MYATT: All right. The statement will be received as Exhibit 16.

(Whereupon, Exhibit No. 16 was marked for identification and was received in evidence.)

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JUDGE MYATT: Are there any questions of Mr. Carver?

Thank you, Mr. Carver.

Dr. Robert Brookman -- I'm sorry. I didn't notice your final note. I'm tired, too.

Firestone does not intend to make a presentation.

Do we have any others?

MS. FERRONE: Not that I know of.

JUDGE MYATT: That, then, concludes all of the individuals that have entered an appearance and indicated that they would make a presentation.

I had a discussion with the OSHA people and the representative from the Solicitor's Office. I will keep the record open for written submissions until March 8th, 1974. All documents should be recived by that date, which is a Friday, by the Occupational Safety and Health Administration, Room 240 -- and again I repeat the address -- 1726 M STreet, N. W., Washington, D. C., Zip 20210.

Yes, sir?

A VOICE: Will these written depositions be included in the transcript of this meeting?

JUDGE MYATT: They will not be in the transcript. They will be part of the official record which will be certified to the Assistant Secretary, but they will not be in the transcript. However, they will be incorporated later -- I don't know. The expert is shaking her head "no," so the

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answer is no.

A VOICE: Thank you.

JUDGE MYATT: I want to thank all of you for your attendance and your cooperation in this matter, and I would also like to thank all of the staff people and the representative from the Solicitor's Office, OSHA, NIOSH, and et cetera.

This hearing is officially adjourned.

(Whereupon, at 5:15 p. m., Friday, February 15, 1974, the hearing in the above-entitled matter was adjourned.)

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CERTIFICATE OF REPORTER

I hereby certify, as the stenographic reporter, that the foregoing proceedings were taken stenographically by me and thereafter reduced to typewriting by me or under my direction; that this transcript is a true and accurate record to the best of my ability.

METROPOLITAN REPORTING SERVICE, INC.

By: Leah S. McClure

Leah S. McClure
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HEALTH DOCKET-80
24 MAY 1974

# CONFIRMED CASES OF LIVER ANGIOSARCOMA AMONG PVC WORKERS

| COUNTRY | CASE # | BIRTH DATE | 1st PVC WORK | DX ANGIO-SARCOMA | AGE AT DX | YRS 1st PVC TO DX | TOT YRS PVC | DATE OF DEATH |
|---|---|---|---|---|---|---|---|---|
| United States | 01 | 00-00-22 | 12-09-48 | 03-00-71 | 49 | 22 | 16 | 03-03-73 |
| United States | 02 | 00-00-34 | 11-15-55 | 05-00-70 | 36 | 14 | 13 | 09-28-71 |
| United States | 03 | 00-00-15 | 11-28-45 | 12-00-73 | 58 | 28 | 28 | 12-19-73 |
| United States | 04 | 00-00-24 | 07-06-52 | 08-00-67 | 43 | 15 | 15 | 01-07-68 |
| United States | 05 | 00-00-12 | 06-19-44 | 04-00-64 | 52 | 20 | 18 | 04-09-64 |
| United States | 06 | 00-00-29 | 01-17-62 | 02-00-74 | 45 | 12 | 12 | ALIVE |
| United States | 07 | 05-03-22 | 08-00-44 | 06-00-68 | 45 | 24 | 18 | 03-23-68 |
| United States | 08 | 05-06-20 | 10-07-46 | 08-00-61 | 41 | 15 | 15 | 08-27-61 |
| United States | 09 | 00-00-31 | 05-28-45 | 03-01-74 | 43 | 29 | 17 | ALIVE |
| United States | 10 | 08-16-13 | 06-00-51 | 05-00-68 | 55 | 17 | 17 | 05-10-68 |
| United States | 11 | 05-27-09 | 10-14-46 | 03-00-70 | 61 | 23 | 23 | 03-18-70 |
| United States | 12 | 11-17-18 | 09-13-49 | 05-00-69 | 50 | 20 | 15 | 05-02-69 |
| United States | 13 | 12-01-21 | 08-19-44 | 03-00-74 | 53 | 30 | 30 | ALIVE |
| W. Germany | 01 | 07-26-31 | 10-14-57 | 00-00-71 | 40 | 14 | 14 | 12-14-71 |
| W. Germany | 02 | 06-04-30 | 10-01-57 | 00-00-69 | 39 | 11 | 11 | 01-25-69 |
| Great Britain | 01 | 00-00-01 | 00-00-46 | 12-00-72 | 71 | 26 | 20 | 12-00-72 |
| Norway | 01 | 12-23-15 | 03-00-50 | 12-20-71 | 56 | 22 | 21 | 01-04-72 |
| Sweden | 01 | 00-00-27 | 00-00-51 | 00-00-70 | 43 | 19 | 18 | 00-00-70 |
| Sweden | 02 | 00-00-11 | 00-00-45 | 00-00-72 | 61 | 27 | 23 | 00-00-72 |

Note: '00' indicates unknown date

| COUNTRY | CASE # | EARLIEST INDICATION OF OTHER POSSIBLE VC RELATED DISEASE | DATE OF EARLIEST INDICATION | 7th Rev. ICD CODE of Cert. | 7th Rev. ICD CODE of Cert. |
|---|---|---|---|---|---|
| US | 08 | | | 228.0 | 227.1 |
| US | 05 | RUQ pain & tender, slight focal Hepatitis, hemangioma of liver | 01-64 | 156.1 | 197.8 |
| US | 05 | | | | |
| US | 04 | Epigastric mass & splenomegaly, hemangioma | 08-67 | 155.0 | 155.0 |
| US | 07 | | | 156.1 | 197.8 |
| US | 10 | | | 581.0 | 571.8 |
| US | 12 | | | 230.x | 230.5 |
| US | 11 | | | 155.0 | 155.0 |
| US | 02 | Hepato-splenomegaly, esophogeal varices | 05-70 | 155.0 | 155.0 |
| US | 01 | Splenomegaly, portal fibrosis, esophogeal varices | 05-65 | 155.0 | 155.0 |
| US | 03 | Hepato-splenomegaly, periportal inflammation & fibrosis | 07-73 | 155.0 | 155.0 |
| US | 06 | | | | |
| US | 09 | Cirhosis of liver (Buerger's Disease, 1966) | 11-68 | | |
| US | 13 | | | | |

HEALTH DOCKET - 36
24 MAY 1974

Dr. Lloyd

May 17, 1974

| COUNTRY | CASE # | FALK'S # | NAME | S.S. # | COMPANY and LOCATION | FIRST EMPLOY DATE | LAST DAY WORKED |
|---|---|---|---|---|---|---|---|
| US | 01 | 4 | | | BF LV | 12-09-43 | 10-19-70 |
| US | 02 | 3 | | | BF LV | 11-15-55 | 05-01-70 |
| US | 03 | 5 | | | BF LV | 11-28-45 | 00-00-00 |
| US | 04 | 2 | | | BF LV | 10-24-49 | 08-19-67 |
| US | 05 | 1 | | | BF LV | 06-19-44 | 00-00-00 |
| US | 06 | 6 | | | BF LV | 01-17-62 | 00-00-00 |
| US | 07 | - | | | UC SC | 00-00-00 | 00-00-00 |
| US | 08 | - | | | GY NF | 10-07-46 | 00-00-00 |
| US | 09 | 7 | | | BF LV | 06-20-44 | 00-00-00 |
| US | 10 | - | | | GY NF | 06-00-51 | 05-00-68 |
| US | 11 | - | | | GY NF | 10-14-46 | 00-00-00 |
| US | 12 | - | | | FS PT | 05-22-46 | 02-19-69 |
| US | 13 | - | | | UC SC | 12-00-42 | 00-00-00 |

Note: "00" indicates unknown date

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Journal of Occupational Medicine

March, 1974 Vol. 16 No. 3

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3959

Special Communication

# Angiosarcoma of Liver in the Manufacture of Polyvinyl Chloride

Three reported cases of angiosarcoma of the liver serve as an alert to the probability that this condition may, in some instances, be causally related to employment in the manufacture of polyvinyl chloride resins

J. L. Creech, Jr., M.D. and M. N. Johnson, M.D.

On January 22-23, 1974, a manufacturer of polyvinyl chloride and copolymers notified it's employees, the National Institute of Occupational Safety and Health, the Kentucky State Department of Labor, and the public, that three workers had died of angiosarcomas of the liver. These cases had as a common denominator employment in the manufacture of polyvinyl chloride resins.

A patient of one of the authors (J.L.C., Jr.) died on September 27, 1971 from an angiosarcoma of the liver. At that time the potential causal relation to the manufacture of polyvinyl chloride resins was not realized. Although other clinical manifestations of exposure to VCM were known (acroosteolysis), only one experimental paper[1] indicated that vinyl chloride may be a carcinogen. The tumors in rats that he described occurred primarily in the skin and were epidermoid in origin.

Eighteen months later on March 3, 1973, a second former employee in the Louisville plant died. Since he was not under our care, no connection was made that the two cases may have had a common origin. When a third patient died on December 19, 1973, the pathologist on gross examination diagnosed an angiosarcoma of the liver. Since all three patients were treated by different physicians, no relationship to exposure to polyvinyl chloride was surmised until the authors, recognizing the rarity of the tumor, and learning that all three had worked in the PVC plant, brought the matter to the attention of the company. Further search indicates that a fourth death from angiosarcoma may have occurred five years earlier (1968), but the death certificate shows primary liver tumor as the cause of death. (Clinical, epidemiologic, toxicological and occupational investigations are being vigorously pursued with regard to other employees who may have been similarly exposed.)

A brief resume of the first case under our care is presented. The history, clinical course, and pathologic findings are consistent with the others who died of angiosarcoma. These cases will be presented in a group and in more detail at a future date.

## Case Report

Patient one, a 36-year old white male, was hospitalized January 5, 1970 because of tarry stools.

**Occupational History.** — The patient had been employed from November 1955 until his illness, except for two lay-offs of nine months in 1958 and six months in 1959, as a chemical helper and operator in the Louisville plant of B. F. Goodrich Chemical Company in the manufacture of polyvinyl chloride resins.

**Present Illness.** — At the time of admission the patient had no complaints except passage of tarry stools. Past history was negative except for an operation for hemorrhoids four years earlier. Physical examination showed pallor, and black stool on rectal examination. Liver and spleen were not palpable. Although upper G-I series was interpreted as normal, a tentative diagnosis was made of bleeding duodenal ulcer.

On diet and medication, the patient had no recurrence of

Dr. Creech is Plant Physician, The B.F. Goodrich Chemical Company, Louisville, Ky. Dr. Johnson is Director of Environmental Health, The B.F. Goodrich Company, Akron, Ohio

Reprint requests to Dept. 0020, Bldg. 5-H, 500 South Main St., Akron, Ohio 44318 (Dr. Johnson).

ovrat bleedi g until May 1, 1970, four months later, when he was readmitted for tarry stools. Again he was found to have marked pallor and tarry stool on rectal examination. At this time the liver was demonstrably enlarged and the spleen was palpable. Blood chemistry studies (SMA-12) were not significantly abnormal; total bilirubin, alkaline phosphatase, LDH, and SGOT were only slightly elevated. G-I series showed only anterior displacement of the stomach, but barium swallow suggested esophageal varices. Intravenous pyelogram was normal; barium enema was normal except for displacement of the splenic flexure by an enlarged spleen. Liver scan on May 4, 1970 was interpreted as being compatible with a large lesion in the left lobe of the liver, extending into the right lobe.

**Operative Procedure and Findings.** — On May 7, 1970 an exploratory laparotomy was carried out. Under anesthesia, the abdomen was entered through a vertical incision. Marked enlargement of the liver and spleen were noted, and the liver was adherent to the anterior surface of the stomach. The liver capsule was quite thickened and tough. There was a gelatinous-like material at the junction of the liver and the stomach. Retroperitoneal nodes were very soft, enlarged, and succulent in appearance. A biopsy of the liver was performed. There was marked degree of hemorrhage following this which was controlled with large sutures through the liver.

## Report of Pathologic Findings

**Gross.** — Specimen is a portion of soft gray and light brown tissue that is 2.2 x 1.9 x 1 cms. at the present state. In some areas it appears to be composed of liver and in others light beige, moderately firm tissue with areas of sponginess and softness.

**Microscopic.** — Most of the tissue pattern of liver is replaced by luxuriantly growing cells forming irregular spaces. These spaces display many trabeculations in their lumina and are lined by pleomorphic malignant endothelial cells. Here and there these cells grow in nearly solid sheets. Elsewhere they line capillaries. There is a newly formed stroma with various degrees of hyalinization here and there.

**Diagnosis.** — "Liver, biopsy of, angiosarcoma (malignant hemangioendothelioma)."

## Clinical Course

Following the laparotomy and biopsy the patient was given 3600 R cobalt and several intra-arterial infusions of 5 FU. During this time there was marked distortion of his blood chemistry with severe diminution of albumin, and marked increase in total bilirubin, alkaline phosphatase, LDH, and SGOT. After a stormy course and several months of convalescence, including several abdominal paracenteses for recurrent ascites, he recovered sufficiently to return to work for a short time. He succumbed to the liver tumor fourteen months post-operatively and died on September 27, 1971.

## Reference

1. Viola PL, Bigotti A and Caputo, A: Oncogenic response of rat skin, lungs, and bones to vinyl chloride. *Cancer Research* 31:516-519, 1971.

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# *Special Communication*

## *Editor's Note*

Professor Cesare Maltoni, Director of the Institute of Oncology of the University of Bologna Italy, presented the results of his unpublished experiments with vinyl chloride on February 15, 1974 at the U.S. Dept. of Labor hearing in Washington, D.C. on "Possible Hazards of Vinyl Chloride Manufacture and Use". His work, which is obviously original and innovative, demonstrated angiosarcoma of the liver and other tumors in experimental animals at air concentrations of vinyl chloride which are known to be present at times in workroom atmospheres. Professor Maltoni describes his methodology as predictive of the carcinogenic potential of airborne chemical contaminants. Professor Maltoni is apparently the first to show the relationship between exposure to vinyl chloride and the appearance of angiosarcoma in mammals.

*—IRT*
*February 21, 1974*

Supplement Exhibit 10(b)
6/25/74 Line 3501

# THE CARCINOGENICITY OF VINYL CHLORIDE

(Statement by Dr. H. F. Kraybill, National Cancer Institute)

The rare and inevitably fatal form of cancer, angiosarcoma of the liver, now implicates vinyl chloride and the polyvinyl chloride residual monomer in occupational exposure to this chemical, which has previously been shown to induce angiosarcoma of the liver in experimental animals. What makes these recent reports on occupationally induced cancers of even more significance is the wide usage of the chemical and its production and economic importance. Only two other chemicals have previously been reported to induce this rare neoplastic lesion; thorotrast, used clinically in cerebral vessel visualization, and an arsenic pesticide used by German vinyard workers. Both vinyl chloride and thorotrast revealed some suggestive evidence on their potential carcinogenic hazard to man through animal experiments. Arsenicals, however, by contrast had no satisfactory animal models to signal their cancer inducing properties in man. The latency period for development of angiosarcoma of the liver in man is comparable for all three etiologic agents.

Earlier studies, about 20 years ago, on vinyl chloride gave indications that this was a hazardous chemical because of its capacity to cause liver and kidney injury, but its carcinogenic hazard was not realized until the studies of Professor Viola revealed some cancers of the skin, bone, and lung in rats; the high dose of 30,000 ppm (4 hours per day for five days a week for 12 months) did not seem to elicit liver cancer. Therefore,

there are indications that vinyl chloride may be a carcinogen for sites other than the liver in man and epidemiological studies may uncover these possibilities.

Professor Maltoni's (Institute of Oncology, Bologna, Italy) recent work has confirmed Viola's original work, but in rats his findings extended observations from reports on cancer of the Zymbal glands (inner ear canal), nephroblastomas and angiosarcomas of the liver and intra-abdominal area, the latter findings even at the low dose of 50 ppm after 1 year exposure. Vinyl chloride is thus capable of inducing angiosarcomas and angiomas of the liver.

The Manufacturing Chemists Association (MCA) supported project at Industrial Biotest Laboratories (bioassay with rats, mice, and hamsters) has established also that angiosarcomas of the liver appeared in mice challenged with vinyl chloride (inhalation studies). The MCA project is significant in that liver angiosarcomas in mice appeared after 6 months exposure at a 50 ppm dose of vinyl chloride (5 days exposure as in other studies to be carried on for 12 months).

In a test group of 200 mice, 40 were either cannibalized or died; of about 18 of these which were examined, two had liver angiosarcomas. Since the MCA project is still continuing, with a longer exposure period extending to 12 months, it may be anticipated that there will be a higher incidence of angiosarcomas for those exposed at the 50 ppm level of vinyl chloride.

Therefore, data from several laboratories fulfills the requirement for a proven carcinogen in that observations were made on angiosarcomas of the liver in several species and strains and there follows a good dose-response relationship, with most recent data showing a response at as low as 50 ppm. With a larger population of animals carried beyond a seven months period, as in the MCA study, it might be expected that the overall incidence could be of the order of 5 percent. Additionally, it would not be surprising if a response as to liver angiosarcoma would be elicited at levels below 50 ppm. At 50 ppm exposure level, the time frame of 6 months for induction of angiosarcomas of the liver in mice is rather unsettling in that long-term continuous exposure (comparable in experimental animals to a time frame for human occupational exposure) may reveal angiosarcomas of the liver at an extended induction period which, in man, could mean a period beyond 20 years.

If one were to assume that in a population occupationally exposed to vinyl chloride there were 100,000 workers involved in such operations as synthesis of vinyl chloride, transporting vinyl chloride, polymerization of vinyl chloride to polyvinyl chloride, and fabrication and storage of PVC with residual VC monomer present, then a 5 percent incidence would be most significant for workers at risk. Such risks do not include those that may arise in non-occupational situations such as polluted air, water, and previously the use of aerosolized products containing VC as a propellant.

Unfortunately, we do not have the epidemiological data relating accurate exposure levels to VC with occurrence of liver angiosarcomas in man. Earlier estimates of exposure levels to VC for plant workers in the past are stated at about 1000 to 2000 ppm and higher. Reports have been received about angiosarcomas of the liver in people not directly receiving plant exposure to vinyl chloride.

Based on what facts we have given, vinyl chloride appears to be a potent hepatocarcinogen. It is capable of inducing non-neoplastic lesions and liver dysfunction, culminating in the irreversible angiosarcoma of the liver. If man responds to low level exposure to vinyl chloride as has the rodent, a low level, continuous exposure of 50 ppm for man would have a high probability for inducing liver cancer.

Certainly, there is little margion for safety if a response can be expected at a level below 50 ppm which is now only a fifty-fold safety factor in terms of proposed standard. According to toxicological principles, were this compound a non-carcinogen, then to establish a tolerance or safe level, there would have to be a 100 to 1 margin of safety in terms of a no-effect level. Obviously, this would put the allowable level at a small fraction of the given standard. Scientifically, for a carcinogen, one would like to see an exposure level that approaches zero. The proposed standard

attempts to achieve, as far as possible within engineering and technological feasibility, a very low order of exposure.

Beyond these attempts to maximize worker protection from vinyl chloride exposure, there are other factors that may be associated with exposure to this hepatocarcinogen. Our knowledge concerning the role of associated contaminants in vinyl chloride in the induction of cancers at various sites, especially the liver, is lacking as is the role of dietary stress such as low protein intake and the insult from alcohol, which may accelerate the formation of the neoplastic lesion or reduce the latency period.

In the pathogenesis of liver cancer evoked by vinyl chloride, some other details are still unknown. For example, little is known about precancerous lesions and the progression of these lesions within a time frame as morphological changes finally are recognized as the irreversible angiosarcoma produced by vinyl chloride. Such information is needed in order to ascertain whether the process can be interrupted or reversed. Additionally, current mechanistic studies may provide a clearer picture on the pathogenesis of this lesion in terms of time and dose-response relationships which may afford, hopefully, some effective measures for cancer control.

STATEMENT OF JEROME H. HECKMAN
KELLER AND HECKMAN
GENERAL COUNSEL OF THE SOCIETY OF THE
PLASTICS INDUSTRY, INC.
PREPARED FOR PRESENTATION AT
DEPARTMENT OF LABOR HEARINGS ON
VINYL CHLORIDE;
OCCUPATIONAL EXPOSURE STANDARD
JUNE 25, 1974

JUDGE MYATT:

My name is Jerome H. Heckman. I am a partner in the Washington law firm of Keller and Heckman and have served as Counsel to The Society of the Plastics Industry for the past twenty years. I am here today to provide an overview of the plastics industry's position with respect to the vinyl chloride problem at hand. Speaking for The Society of the Plastics Industry, we are anxious that the testimony to follow be viewed in its proper and total perspective. This is because we believe it essential that any final standard adopted by the government take into balanced account the full spectrum of public and employee health considerations, social and economic impact, as well as other public interest factors.

THE TASK OF THE DEPARTMENT IN THIS CASE IS ANYTHING BUT A SIMPLE ONE. IT MUST BALANCE THE INTERESTS INVOLVED AND REACH WELL-REASONED DECISIONS, BUT A MAJOR DIFFICULTY IS THAT MANY OF THESE DECISIONS WILL NECESSARILY HAVE TO BE BASED ON THE RULES OF PROBABILITY RATHER THAN IRREFUTABLE FACT. MUCH OF THE SCIENTIFIC DATA OBTAINED BY RESEARCHERS TO DATE IS QUITE INCONCLUSIVE. A GREAT DEAL OF ADDITIONAL DATA REMAINS TO BE ACQUIRED AND EVALUATED. AT THIS PRECARIOUS STATE OF OUR KNOWLEDGE WE BELIEVE THAT MISPLACED RELIANCE ON MERE SUSPICIONS RATHER THAN PROVEN DATA, OR PRECIPITOUS AND EMOTIONAL REACTION TO SUCH INCOMPLETE INFORMATION, TOGETHER WITH A NARROWLY CONSTRUED INTERPRETATION OF INTERESTS, COULD LEAD TO MAJOR ECONOMIC CONSEQUENCES. SUCH RESULTS FREQUENTLY FLOW FROM UNDULY HARSH MEASURES.

AS MR. HARDING HAS ALREADY NOTED, WE BELIEVE THAT THE PLASTICS INDUSTRY HAS MOVED RESPONSIBLY IN ALL RESPECTS TO OBTAIN HARD DATA AND TO PLAN TO DEAL PROMPTLY AND EFFECTIVELY WITH THE VINYL CHLORIDE QUESTION. WE INTEND TO SHOW, THROUGH THE WITNESSES WHO FOLLOW ME, THAT WE HAVE WITHIN THE TIME CONSTRAINTS PLACED UPON GOVERNMENT AND INDUSTRY ALIKE, ATTEMPTED TO MAKE THE RECORD HERE AS OBJECTIVE, COMPREHENSIVE AND COMPLETE AS IS POSSIBLE. YOU MAY ALSO RELY ON THIS INDUSTRY TO RECOGNIZE THAT SO LONG AS ANY DOUBT REMAINS AS TO

SAFETY LEVELS AND EMPLOYEE OR OTHER EXPOSURE, IT IS INCUMBENT UPON MANUFACTURERS TO MAKE THE WORKPLACE AND GENERAL ENVIRONMENT AS RISK-FREE AS FEASIBLE.

IT IS CLEAR THAT CONGRESS, IN ENACTING PUBLIC LAW 91-596, AND THE COURTS WHICH HAVE THUS FAR INTERPRETED IT AUTHORITATIVELY, RECOGNIZED THAT THE SECRETARY OF LABOR MUST, IN ESTABLISHING PROTECTIVE STANDARDS, CONSIDER THE FEASIBILITY OF MEETING THEM. THE TERM "FEASIBILITY" HERE ENCOMPASSES HEALTH, TECHNOLOGICAL, AND ECONOMIC CONSIDERATIONS. THE TASK OF THE SECRETARY HAS BEEN VERY APTLY STATED IN THE APRIL 15, 1974 DECISION OF THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT IN INDUSTRIAL UNION DEPARTMENT, AFL-CIO, ET AL. V. HODGSON (NO. 72-1713). ON PAGES 19 AND 20 OF THAT DECISION, THE FOLLOWING LANGUAGE PROVIDES A REASONABLE GUIDELINE FOR DECISION-MAKING IN CASES SUCH AS THE INSTANT ONE:

> *There can be no question that OSHA represents a decision to require safeguards for the health of employees even if such measures substantially increase production costs. This is not, however, the same thing as saying that Congress intended to require immediate implementation of all protective measures technologically achievable without regard for their economic impact. To the contrary, it would comport with common usage to say that a standard that is prohibitively expensive is not 'feasible' (footnote omitted). Senator Javits, author of the amendment that added the phrase in question to the Act, explained it in these terms:*

> *As a result of this amendment the Secretary, in setting standards, is expressly required to consider feasibility of proposed standards. This is an improvement over the Daniels bill, which might be interpreted to require absolute health and safety in all cases, regardless of feasibility, and the Administration bill, which contains no criteria for standards at all.*
>
> *S. Rep. No. 91-1282, 91st Cong., 2d Sess., p. 58; Legis. Hist. at 197.*
>
> *The thrust of these remarks would seem to be that practical considerations can temper protective requirements. Congress does not appear to have intended to protect employees by putting their employers out of business--either by requiring protective devices unavailable under existing technology or by making financial viability generally impossible. (Emphasis supplied.)*

MANY OTHER PARTS OF THIS DECISION ARE ALSO DIRECTLY IN POINT. THUS, ON PAGES 12 AND 13 OF THE COURT'S OPINION, IT IS NOTED THAT WHERE EXPLICIT FACT-FINDING IS IMPOSSIBLE, AND DETERMINATIONS MUST BE MADE "ON THE FRONTIERS OF SCIENTIFIC KNOWLEDGE," POLICY JUDGMENTS MUST BE MADE AND ESOTERIC ABSOLUTISM FORSAKEN. LIKEWISE, ON PAGE 23 OF THE OPINION IT IS WELL NOTED THAT, ALTHOUGH EMPLOYEES OBVIOUSLY SHOULD NOT BE NEEDLESSLY EXPOSED TO RISK, WHERE THE DEGREE OF RISK IS INDETERMINATE, SOME ELEMENT OF IT MAY HAVE TO BE COUNTENANCED FOR A TIME WHEN IT IS INFEASIBLE TO ELIMINATE IT TOTALLY, AND A TRANSITION PERIOD IS REQUIRED FOR STUDY AND IMPROVEMENTS.

IT IS OUR POSITION THAT THE RECOMMENDATIONS TO BE MADE HEREAFTER RECOGNIZE THESE CRITERIA, BUT ALSO BESPEAK A TOTAL INDUSTRY COMMITMENT TO INSTITUTE APPROPRIATE SAFEGUARDS WHILE CONCURRENTLY MOVING FORWARD TO DETERMINE WHAT DATA IS ADDITIONALLY REQUIRED TO MAKE EVEN SOUNDER JUDGMENTS. THE INDUSTRY IS MOVING DECISIVELY TO PROVIDE IMMEDIATE PROTECTIVE ACTION. FURTHER, SCIENTIFIC STUDIES YET TO BE COMPLETED MAY WELL PROVE THAT THE HAZARD HAS BEEN OVERESTIMATED. NEVERTHELESS, WHILE DOUBTS REMAIN, OUR AIM IS TO ASSURE THE PUBLIC AT LARGE, THE INDUSTRY'S EMPLOYEES, AND THE GOVERNMENT THAT THE PLASTICS INDUSTRY HAS BEEN AND WILL CONTINUE TO BE DILIGENT IN TAKING PROMPT AND FEASIBLE STEPS TO MINIMIZE ANY POTENTIAL HEALTH HAZARD.

THE WITNESSES TO FOLLOW WILL DISCUSS IN DETAIL THE FEASIBILITY OF MEETING REASONABLE VINYL MONOMER EXPOSURE LIMITATIONS; HOW PROTECTION CAN BE AND WILL BE AFFORDED EMPLOYEES WHERE SHORT-TERM EXCURSIONS OCCUR ABOVE THE LIMITATIONS WE WILL RECOMMEND; WHY THE EXPOSURE LIMITATIONS IN THE PROPOSED PERMANENT STANDARD PUBLISHED ON MAY 10 ARE NOT REASONABLE, WOULD LIKELY ELIMINATE THE INDUSTRY TO THE GREAT DETRIMENT OF THE COUNTRY, AND SHOULD NOT BE IMPOSED ON THE BASIS OF THE TOXICOLOGICAL DATA PRESENTLY AT HAND; AND WHY THE BREADTH OF COVERAGE OF THE PROPOSED STANDARD MAY SAFELY

BE REDUCED SO AS TO ELIMINATE APPLICATION OF MANY OF THE BURDENSOME REQUIREMENTS IN THE DRAFT STANDARD TO CERTAIN MANUFACTURERS AT THE END OF THE PROCESSING LINE. THESE FIRMS, IT WILL BE SHOWN, HAVE NO REAL VINYL MONOMER EXPOSURE PROBLEM, EVEN THOUGH THEY MANUFACTURE PRODUCTS THEORETICALLY "CAPABLE OF RELEASING DETECTABLE LEVELS" OF MONOMER.

IN TESTIMONY TO BE PRESENTED NEXT BY MR. ANTON VITTONE OF B. F. GOODRICH HE WILL FULLY COVER THE CURRENT STATE OF THE ART AND THE CAPABILITY OF THE INDUSTRY TO MEET AND ULTIMATELY IMPROVE UPON THE EXPOSURE LIMITATIONS WE RECOMMEND. IT SHOULD BE NOTED THAT THE SOCIETY IS AWARE OF ADDED TESTIMONY THAT WILL BE PRESENTED ON THIS SUBJECT IN THE CASES PREPARED BY VARIOUS INDIVIDUAL COMPANIES WHICH ARE APPEARING HERE.

IT WILL SUBSEQUENTLY BE DEMONSTRATED BY OUR SUCCEEDING WITNESSES THAT THE EXPOSURE LIMITATIONS, TIMETABLE FOR REDUCTIONS, AND REVISED WORK PRACTICE RULES WHICH WE ADVOCATE WILL PREVENT THE VIRTUAL ECONOMIC CHAOS THAT COULD RESULT IF THE PRESENTLY PROPOSED STANDARD WERE ADOPTED. WE SUBMIT THAT OUR ALTERNATIVE PROPOSALS CAN BE ACHIEVED WITH REASONABLE ASSURANCE THAT NO UNDUE HAZARD WILL ARISE OR BE ALLOWED TO CONTINUE WITH REGARD TO EMPLOYEE SAFETY. OUR MEDICAL EXPERTS WILL URGE UPON THE DEPARTMENT THAT THE HUMAN

EXPERIENCE DATA WE HAVE ASSEMBLED--AND WHICH WE BELIEVE IS ENTITLED ON TOXICOLOGICAL GROUNDS TO GREATER WEIGHT THAN INCONCLUSIVE ANIMAL TEST DATA IN CIRCUMSTANCES LIKE THOSE PRESENTED HERE--JUSTIFIES THOSE EXPOSURE LIMITATIONS THE INDUSTRY CONSIDERS FEASIBLE NOW AND IN THE FUTURE. AGAIN, WE RESPECTFULLY SUBMIT THAT THIS EVIDENCE, TAKEN IN CONTEXT, MUST OVERRIDE AND OBVIATE THE IMPOSITION OF EXCESSIVELY RESTRICTIVE EXPOSURE LIMITS OR WORK PRACTICES (SUCH AS A REQUIREMENT FOR FULL-TIME USE OF RESPIRATORS) WHICH WOULD LIKELY SHUT THE INDUSTRY DOWN WITH THE RESULTANT DISRUPTIVE CONSEQUENCES WHICH WILL BE PROJECTED AND EXPLAINED BY MR. VINCENT FICCAGLIA OF ARTHUR D. LITTLE COMPANY.

TESTIMONY AS TO APPROPRIATE MEASUREMENT TECHNIQUES AND POLICIES WILL BE SUPPLIED BY DR. RUDOLPH STEHL OF THE DOW CHEMICAL COMPANY AND WILL LEAD TO OUR MAKING SPECIFIC RECOMMENDATIONS IN THIS AREA. THE PURPOSE HERE WILL BE TO ADD CLARITY AND SPECIFICITY TO THE FINAL STANDARD. SIMILARLY, DRS. JOSEPH TOMASHEFSKI AND ROBERT SOULE WILL EXPLAIN WHY FULL-TIME USE OF RESPIRATORS WOULD BE LIKELY TO HAVE BOTH SIGNIFICANT AND IMMEDIATE ADVERSE IMPACT ON WORKER HEALTH AND SAFETY. DR. ROGER STRASSBURG WILL INFORM YOU AS TO HOW SO-CALLED CANISTER-TYPE RESPIRATORS CAN BE EMPLOYED AND RELIED UPON FOR SHORT PERIODS OF TIME UNDER THE TYPE OF PERMANENT STANDARD THE INDUSTRY CAN SUPPORT.

OTHER TESTIMONY FROM A SERIES OF WITNESSES WHO HAVE BOTH OBJECTIVE TEST DATA AND PERSONAL EXPERTISE PERTAINING TO THE HANDLING AND USE OF PVC FOR FABRICATION WILL, WE BELIEVE, CONVINCE THE DEPARTMENT OF THE ADVISABILITY AND REASONABLENESS OF MAKING CLARIFYING CHANGES IN THE STANDARD SO THAT ITS APPLICATION WILL, WITH PERHAPS MINOR EXCEPTIONS, BE LIMITED TO THOSE WHO MAKE AND SELL ONLY MONOMER AND POLYMERS.

THIS WILL BE THE THRUST OF OUR CASE. IT IS ONE IN WHICH WE HAVE FAITH; ONE THAT WE BELIEVE THE INDUSTRY'S WORKERS SHOULD SUPPORT; AND ONE THAT, IF APPROPRIATELY REFLECTED IN THE STANDARD ADOPTED, WOULD ALLOW THE INDUSTRY TO CONTINUE TO SERVE THE PUBLIC INTEREST.

WHILE OUR MAJOR PLEA IS FOR A CHANGE IN THE "NO DETECTABLE LIMITS" CONCEPT IN FAVOR OF WHAT IS TRULY FEASIBLE AND, THEREFORE, TECHNICALLY AND LEGALLY SOUND, WE ALSO STRONGLY URGE THAT CERTAIN OTHER ELEMENTS IN THE STANDARD BE CHANGED. SOME OF THESE CHANGES WE BELIEVE ARE NECESSARY TO AID IN SIMPLE UNDERSTANDING OF WHAT IS REQUIRED; OTHERS ARE URGED TO ALLOW A MORE REASONABLE HANDLING OF DAY-TO-DAY PROBLEMS IN A WAY THAT IS CONSISTENT WITH PRACTICABILITY, AND CONTINUED INDUSTRY VIABILITY.

THE CHANGES RECOMMENDED ARE IN ALL CASES SUBSTANTIVE AND NECESSARY AS WE SEE THEM. AS TO ALL OF THESE, I WOULD ASK YOUR HONOR TO RECEIVE FOR THE RECORD THE SET OF STANDARD REVISION RECOMMENDATIONS ATTACHED TO MY STATEMENT. OUR HOPE IS THAT THIS WRITTEN TABULATION WILL FACILITATE RECOGNITION OF SUCH LANGUAGE IN THE PROPOSED STANDARD WHICH WE DEEM UNDULY BURDENSOME, UNNECESSARY, OR UNCLEAR, AND WILL AID THE DEPARTMENT IN CONSIDERING OUR SPECIFIC RECOMMENDATIONS FOR CHANGES.

FOR THE MOST PART, THE RECOMMENDED REVISIONS WILL BE SELF-EXPLANATORY IN LIGHT OF THE EVIDENCE TO BE PRESENTED VERY SHORTLY. HOWEVER, THERE ARE A FEW AREAS WHICH I WILL DISCUSS NOW SINCE THEY ARE IMPORTANT TO THE INDUSTRY AND ARE NOT BEING DEALT WITH DIRECTLY IN THE STATEMENTS OF OUR OTHER WITNESSES. I BELIEVE I CAN SUMMARILY ALLUDE TO THESE SITUATIONS AND ASK THAT YOU BEAR WITH ME WHILE I ATTEMPT TO DO SO:

1. WITH RESPECT TO THE PROPOSED PARAGRAPH 1910.93Q(A)(1), DEALING WITH THE SCOPE OF THE STANDARD, SUBSEQUENT TESTIMONY WILL INDICATE WHY IT IS BELIEVED EXCESSIVELY AND INFEASIBLY BROAD. IT SHOULD ENCOMPASS ONLY THOSE AREAS AND

OPERATIONS THAT POSE OR MAY REASONABLY BE EXPECTED TO POSE PROBLEMS, AND BE MADE INAPPLICABLE TO CERTAIN TYPES OF OPERATIONS, PRIMARILY PROCESSING AND FABRICATION PLANTS.

2. WITH RESPECT TO PARAGRAPH (B)(2), IT SHOULD BE REVISED TO ALLOW FOR THE RELATIVELY INFREQUENT BUT NECESSARY ENTRY OF CONTRACTORS, TRUCK DRIVERS AND SERVICE PERSONNEL, WHOSE SERVICES ARE REQUIRED FROM TIME TO TIME IN NORMAL OPERATIONS.

3. PARAGRAPH (B)(4) CONTAINS PARTICULARLY VEXATIOUS LANGUAGE AND WHAT AMOUNTS TO A WHOLLY AMBIGUOUS AND UNWORKABLE DEFINITION OF "CONTAMINATED" BY EMPLOYING THE OPEN-ENDED CONCEPT THAT AN AREA OR PRODUCT COULD BE CONSIDERED CONTAMINATED IF IT IS "CAPABLE OF RELEASING A DETECTABLE LEVEL OF VINYL CHLORIDE." THIS NOTION IS INCONSISTENT WITH OTHER OSHA STANDARDS IN ITS LACK OF FINITENESS.

THERE ARE SITUATIONS WHERE SUBSTANCES BELIEVED TO BE 100 TO 1000 TIMES

AS CARCINOGENIC AS VINYL CHLORIDE MAY ULTIMATELY BE SHOWN TO BE ARE TREATED MUCH MORE SENSIBLY. FOR THIS REASON, WE URGE THAT THIS DEFINITION BE ALTERED SO THAT IT REFLECTS THE AVERAGE EXPOSURE LIMIT TO BE ADVANCED BY MR. VITTONE AS TO VINYL MONOMER, AND THAT NO AREA BE CONSIDERED CONTAMINATED WHERE THE POLYVINYL CHLORIDE RECEIVED OR USED THEREIN CONTAINS LESS THAN 0.1% RESIDUAL MONOMER NOW, OR LESS THAN 0.01% RESIDUAL MONOMER BY OCTOBER 5, 1977. THE LIMITATIONS SUGGESTED BY THIS TYPE OF DEFINITION WOULD BE AS STRINGENT IMMEDIATELY AS THOSE IMPOSED ON SUCH KNOWN CARCINOGENS AS 4-AMINODIPHENYL--"THE MOST HAZARDOUS AROMATIC AMINE REGARDING CARCINOGENIC POTENTIAL," (SEE SECTION 1910.93(K)) AND BIS-CHLOROMETHYL ETHER, (SEE SECTION 1910.93(H)). BY 1977 IT WOULD BE TEN TIMES MORE STRINGENT BARRING THE ACQUISITION OF NEW DATA WHICH MAY WELL PROVE THAT THE 0.1% LIMITATION IS UNDULY HARSH.

4. THE DEFINITION OF "EMERGENCY" IN PARAGRAPH (B)(8) SHOULD BE ALTERED FURTHER,

EVEN ASSUMING THAT OTHER PROVISIONS IN THE STANDARD ARE CHANGED SO AS TO REFLECT FEASIBLE EXPOSURE LIMITS INSTEAD OF THE "NO DETECTABLE" CONCEPT PRESENTLY CONTEMPLATED. AS THE DEFINITION NOW READS, A MINOR SPILL OR LEAK WOULD CONSTITUTE AN "EMERGENCY" AND COULD TRIGGER MAJOR ACTION UNNECESSARILY. IN LIEU OF THIS DEFINITION, IT IS RESPECTFULLY URGED THAT THE STANDARD BE CHANGED SO THAT IT WILL FOLLOW THE NIOSH RECOMMENDATIONS OF MARCH 11, 1974 WHEREIN AN EMERGENCY WAS DEFINED AS "... AN UNFORESEEN CIRCUMSTANCE OR SET OF CIRCUMSTANCES, SUCH AS A RUPTURED TRANSFER LINE, RESULTING IN THE RELEASE OF VINYL CHLORIDE SUFFICIENT TO PRODUCE ACUTE SYMPTOMS AMONG WORKERS EXPOSED OR HAVING CONTACT WITH VINYL CHLORIDE."

5. WITH RESPECT TO PARAGRAPH (B)(10), AN IMPORTANT CLARIFICATION SHOULD BE MADE TO REFLECT ACTUAL INDUSTRY PRACTICES. THE DEFINITION AS WRITTEN WOULD DEFINE AS FABRICATED PRODUCTS "FILM, SHEET, BLOCK, BAR, OR EXTRUSION STOCK." SO THAT THIS DEFINITION

WILL COMPORT WITH INDUSTRY TERMINOLOGY, AND THEREBY AVOID UNINTENTIONAL CONFUSION, THE SECTION SHOULD BE REVISED IN PERTINENT PART TO COVER AS FABRICATED PRODUCTS "FILM, SHEET, BLOCK, BAR, EXTRUDED STOCK, AND DICED OR PELLETIZED COMPOUNDS."

6. REGARDING ALL OF SECTION (E), THE TABLE ATTACHED TO THIS TESTIMONY REFLECTS RECOMMENDED CHANGES DEEMED ESSENTIAL, AS WILL BE INDICATED BY DR. STEHL OF THE DOW CHEMICAL COMPANY, THIS BEING THE THRUST OF HIS PRESENTATION. IN ADDITION, OF COURSE, THE RECOMMENDATION SET FORTH IN THE ATTACHMENT TO MY TESTIMONY REFLECTS THE INDUSTRY POSITION FAVORING CONSTANT SEQUENTIAL MONITORING, WITH SPECIFIED PROCEDURES, IN LIEU OF THE PRESENTLY PROPOSED 95% CONFIDENCE LEVEL REQUIREMENT WHICH WE CONSIDER TO BE VAGUE AND, PRACTICALLY SPEAKING, MEANINGLESS.

7. PARTICULAR MENTION MUST BE MADE HERE RELATIVE TO THE SUBJECT OF EMPLOYEE OBSERVATION OF MONITORING AND MEASURING. CERTAINLY THE INDUSTRY DOES NOT TAKE ISSUE

WITH THE STATUTORY RIGHT OF EMPLOYEES TO
BE ADEQUATELY ASSURED ABOUT MONITORING
PROCEDURES USED FOR THEIR PROTECTION AND
TO OBSERVE THE SAME IN A REASONABLE FASHION.
IT IS INTERESTING TO NOTE, HOWEVER, THAT
THE PROPOSED STANDARD ITSELF DOES NOT EVEN
INCLUDE THE WORD "REASONABLE" IN CONNECTION
WITH THE PHRASE "OPPORTUNITY TO OBSERVE"
[illegible] ONE OF THE MOST IMPORTANT
[illegible] IN THE
STANDARD [illegible].

IN [illegible]
FOR A [illegible]
TIVE MONITORING [illegible]
SO AS TO AVOID UNNECESSARILY [illegible]
ABUSES. [illegible] CONCERNED EASILY RECOGNIZE THAT THE
PRESENT LANGUAGE [illegible] EACH EMPLOYEE OR HIS
SECRETARY IS ENTITLED TO REVOKE PASSWORDS (2) AND
(3) SO THAT THE OBSERVATION OF THE MONITORING
WILL BE HANDLED BY AN ELECTED EMPLOYEE.
IN OTHER RESPECTS, IT IS SUBMITTED THAT THE
LANGUAGE SUGGESTED IN THE ATTACHED TABLE
WILL BE MORE APPROPRIATE AND SUFFICE FOR
EMPLOYEE PROTECTION WITHIN THE CONTEMPLATION
OF THE STATUTE AND APPLICABLE REGULATIONS.

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8. THE MATTER OF SIGNS AND LABELS COVERED IN SECTION (K) OF THE PROPOSED PERMANENT STANDARD IS OF ENORMOUS CONCERN TO THE INDUSTRY. IN AN ERA WHEN THE PUBLIC, INCLUDING THE WORK POPULATION, HAS BEEN SO BOMBARDED BY PEREMPTORY WARNINGS AND CAUTIONARY LABELS TO THE POINT WHERE ALL CHARACTERIZING LANGUAGE TENDS TO BECOME MEANINGLESS (EXCEPT TO REGULATORS IN OTHER FIELDS AND TO PRODUCT LIABILITY ATTORNEYS), WE ARE UNABLE TO SEE HOW THE PUBLIC INTEREST WOULD BE SERVED BY THE TYPE OF SIGN AND LABELING LANGUAGE THUS FAR RECOMMENDED.

WHILE THIS LANGUAGE MAY BE DEEMED CONSISTENT WITH REQUIREMENTS FOR PROVEN AND HIGHLY POTENT CARCINOGENS, IT IS CERTAINLY NOT CONSISTENT WITH THE TYPE OF SIGN AND LABELING REQUIREMENTS DEEMED ACCEPTABLE BY OSHA IN CASES WHERE LESS INFORMED PARTIES ARE APT TO BE VIEWING SUCH SIGNS AND LABELS REGULARLY. THUS, FOR EXAMPLE, IN THE CASE OF ASBESTOS WHERE IT WAS RECOGNIZED THAT CONTAINERS, SHIPPING VEHICLES, AND OTHER MEDIA WITH PUBLIC

VISIBILITY WOULD BE INVOLVED, THE DEPARTMENT ACCEPTED AND THE U. S. COURT OF APPEALS APPROVED LANGUAGE WHERE THE EMPHASIS WAS UPON THE PRECAUTIONARY STEPS TO BE TAKEN, NOT THE NATURE OF THE SUBSTANCE. COMMON SENSE WOULD APPEAR TO DICTATE THAT EXPLICIT INSTRUCTIONS ON HOW TO DEAL WITH A SUBSTANCE OR PRODUCT WILL BE MORE HELPFUL TO THOSE WHO MIGHT BE EXPOSED THAN WILL SCARE LABELS WHICH INDICATE ONLY THAT SOMETHING IS TO BE FEARED, RATHER THAN DEALT WITH REASONABLY.

FOR THIS REASON, AND ON THE BASIS OF THE PRACTICES WHICH EXIST WHERE OTHER HAZARDOUS SUBSTANCES MAY HAVE TO BE ENCOUNTERED BY EMPLOYEES OF VARYING DEGREES OF TECHNICAL EXPERTISE, AND SUSCEPTIBILITY TO ANXIETY, IT IS RECOMMENDED THAT THE CONCEPT OF EMPHASIZING THE IDEA OF "CANCER SUSPECT AGENT" BE REPLACED SO THAT ANY REGULATED AREA SIGNS REQUIRED BY THE STANDARDS WOULD READ:

Vinyl Chloride Vapor Hazard.
Use Assigned Protective Equipment When Alarm
Signal Is Activated
When Signal Is Activated, Do Not Remain In Alarm Area
Unless Your Work Requires It.
Breathing Excessive Quantities of Vinyl Chloride Vapor
May Be Hazardous To Your Health

WITH RESPECT TO WARNING LABELS OR SIGNS TO BE PLACED ON SHIPPING CONTAINERS OF ANY TYPE FOR VINYL CHLORIDE MONOMER, THE FOLLOWING LANGUAGE IS SUGGESTED:

Vinyl Chloride
Danger
Extremely Flammable Gas Under Pressure
May Polymerize With Explosive Force
Avoid Contact With Liquid Or Vapor Unless Fully
Protected By Authorized Equipment.
In The Event Of Acute Exposure Seek Medical
Assistance Immediately.

WITH RESPECT TO WARNING LABELS OR SIGNS TO BE PLACED ON SHIPPING CONTAINERS OF ANY TYPE FOR POLYVINYL CHLORIDE, THE FOLLOWING LANGUAGE IS SUGGESTED:

Polyvinyl Chloride
Caution
Contains Vinyl Chloride
Avoid Breathing Vapor Or Dust
Closed Containers Of Polyvinyl Chloride May Contain
Vapor Levels Of Vinyl Chloride Which May
Be Hazardous To Your Health.
Open Only In Well-Ventilated Areas Or Wear Respiratory
Protection.

THE IMPORTANCE OF THE LABELING REQUIREMENTS IS DIFFICULT TO OVER-EMPHASIZE FOR A VARIETY OF REASONS. CERTAINLY THE MOST IMPORTANT ONE HAS BEEN STATED ABOVE, I.E. LABELING SHOULD BE DESIGNED TO PROVIDE THOSE WHO NEED THE INFORMATION WITH METHODS FOR DEALING WITH THE PROBLEM, RATHER THAN A BASIS UPON WHICH TO PANIC BECAUSE OF A DISEASE CHARACTERIZATION.

IN LIGHT OF THE ECONOMIC IMPORTANCE OF ASSURING CONTINUED PRODUCTION AND SUPPLY OF POLYVINYL CHLORIDE RESINS WITHOUT ADDING UNNECESSARILY TO THE COSTS THEREOF, IT MUST ALSO BE BORNE IN MIND THAT CHARACTERIZING THE MATERIAL AS PRESENTLY PROPOSED COULD LEAD TO THE IMPOSITION OF TRANSPORTATION BANS BY SOME STATES--PROPOSALS TO DO PRECISELY THIS HAVING ALREADY BEEN ADVANCED IN THE STATE OF NEW JERSEY--AND WOULD UNDOUBTEDLY ARM THE OVERZEALOUS WITH WHAT THEY MIGHT CONSIDER A PRIMA FACIE CASE IN SOME SPECIOUS PRODUCTS LIABILITY PROCEEDINGS. IT IS IMPOSSIBLE FOR US TO SEE HOW THIS WOULD SERVE THE OBJECTIVES OF THE OCCUPATIONAL

SAFETY AND HEALTH ACT OR ANY ASPECT OF THE PUBLIC INTEREST.

WE NOW ASK THAT CAREFUL ATTENTION BE GIVEN TO THE PRESENTATIONS OF THE REMAINDER OF OUR PANEL AND URGE THAT ANY PERMANENT STANDARD ADOPTED TAKE INTO CAREFUL ACCOUNT ALL OF THE INFORMATION SO PROVIDED.

| I<br>Proposed Standard<br>(Objections Underlined) | II<br>Recommended Changes 1/ | III<br>Comments |
|---|---|---|
| § 1910.93q Vinyl Chloride.<br>(a) *Scope and application.* (1) This section applies to any area or operation in which vinyl chloride (chloroethene), Chemical Abstracts Service Registry No. 75014, is manufactured, reacted, released, repackaged, stored, or used, including areas and operations involving polyvinyl chloride where detectable levels of vinyl chloride are released. | (a)(1)...which contains 0.1% or more of residual vinyl chloride on and after Oct. 5, 1974, and which contains 0.01% or more of residual vinyl chloride on and after Oct. 5, 1977. | |
| (2) This section does not apply to the handling or use of fabricated products made entirely or in part of polyvinyl chloride. (a)(2) | (a)(2)...nor to the handling or use of polyvinyl chloride that complies with the residual vinyl chloride limitations set forth in paragraph (a)(1). | |
| | Add a new paragraph (b) to read as follows and reletter all succeeding paragraphs accordingly:<br><br>* * *<br><br>(b) Permissible exposure to vinyl chloride.<br><br>(b)(1) For polyvinyl chloride production facilities.<br><br>(i) Standard effective Oct. 5, 1974. The maximum concentration of vinyl chloride to which any employee may be exposed shall not exceed 40 ppm nor shall the time-weighted average concentration exceed 25 ppm. | This will set forth the exposure limitations recommended by the various witnesses. It also reflects the recommendations of different standards for different manufacturing operations to set work place levels as low as feasible. |

1/ The recommended changes are submitted as substituted language for that underlined in Column I unless it is indicated in Column I that language from Column II is submitted to be added to the proposed section as in the case of Section (a)(2).

(ii) Standard effective Oct. 5, 1975. The maximum concentration of vinyl chloride to which any employee may be exposed shall not exceed 25 ppm.

(iii) Standard effective Oct. 5, 1976. The maximum concentration of vinyl chloride to which any employee may be exposed shall not exceed 25 ppm nor shall the time-weighted average concentration exceed 10 ppm.

(b)(2) For vinyl chloride production facilities.

(i) Standard effective Oct. 5, 1974. The maximum concentration of vinyl chloride to which any employee may be exposed shall not exceed 25 ppm nor shall the time-weighted average concentration exceed 10 ppm.

(ii) Standard effective Oct. 5, 1975. The maximum concentration of vinyl chloride to which any employee may be exposed shall not exceed 10 ppm nor shall the time-weighted average concentration exceed 5 ppm.

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| I | II | III |
|---|---|---|
| (b) *Definitions.* (1) "Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor or his designee. | | |
| (2) "Authorized employee" means an employee whose duties require him to be in the regulated area and who has been specifically assigned by the employer; and any employee who enters such an [illegible] | (c)(2) "Authorized personnel"...; and other personnel such as truck drivers, contractors, service personnel and others whose legitimate duties require their occasional presence in operating areas. | |
| (3) "Closed container" means any container which prevents the release of vinyl chloride to the environment. | | |
| (4) "Contaminated" means capable of releasing a detectable level of vinyl [illegible] | (c)(4)... means, a level of vinyl chloride in the workplace or materials that produce a level of vinyl chloride in the workplace in excess of the limitations set forth in paragraph (b). | |
| (5) "Decontamination" means reduction of vinyl chloride concentrations to less than detectable levels. | (c)(5)... the levels set forth in paragraph (b). | |
| (6) "[illegible] means an airborne [illegible] | (c)(6)... [Omit] | This entire subparagraph will not be required if the proposed limitations (paragraph(b)) are adopted. |
| (7) "Director" means the Director, National Institute for Occupational Safety and Health, or any person directed by him or the Secretary of Health, Education, and Welfare to act for the Director. | | |
| (8) "Emergency" means an unforseen circumstance or set of circumstances, resulting in the release of vinyl chloride [illegible] | (c)(8)... such as a ruptured transfer line, resulting in the release of vinyl chloride sufficient to produce acute symptoms among workers exposed to or having contact with the vinyl chloride. | This reflects the NIOSH March 11, 1974 definition of an emergency. |
| (9) "Exposure" means actual contact with vinyl chloride when unprotected by [illegible] personal protective equipment and clothing. | (c)(9)... liquid vinyl chloride or inhalation of vinyl chloride gas in excess of permissible levels set forth in paragraph (b). | Personnel using protective equipment are not exposed to the vinyl chloride. |
| (10) "Fabricated product" means a finished product or part of such product, made of polyvinyl chloride, entirely or in part, including semifinished products such as film, sheet, block, bar, or extrusion stock. | (c)(10)...extruded stock, or diced or pelletized product made from the foregoing. | This corresponds to commercial practice and nomenclature. |

2/ (d) *Regulated areas.* (1) A regulated area shall be established where (i) vinyl chloride is manufactured, reacted, released, repackaged, stored, or used; or (ii) polyvinyl chloride capable of releasing detectable levels of vinyl chloride is manufactured, reacted, released, repackaged, stored, or used.

(2) Access to regulated areas shall be limited to authorized employees.

(3) A daily roster of employees entering regulated areas shall be maintained. Such daily rosters, or summaries thereof, shall be kept for at least 20 years.

(e) *Monitoring.* (1) Every regulated area shall be monitored for detectable levels of vinyl chloride.

(2) The monitoring shall assure that any employee may be identified for each period and each employee's exposure level may be determined.

2/
(e)(1)(ii)...containing levels of residual vinyl chloride in excess of the limits set forth in paragraph (a)(1)...

(e)(2)...personnel.

(e)(3)...personnel whose duties regularly require their entry into regulated areas shall be made and maintained... 30...

(f)(1)...constantly, sequentially monitored for levels of vinyl chloride at appropriate intervals so as to yield readings taken over a 10 minute integrated sample period representative of vinyl chloride concentrations in the area, or the equivalent thereof.

(f)(2) Delete, and add the following:

(f)(2)(i) Probes shall be so located in every regulated area as to provide a statistically valid sample of the workplace atmosphere. Analysis shall be conducted on samples obtained from each probe in a sequential manner so that the atmosphere at each site is analyzed.

(f)(2)(ii) The analytical instruments shall be periodically checked and re-calibrated to assure proper functioning in accordance with good analytical practices.

(f)(2)(iii) The monitoring equipment shall produce an audible and visible alarm in any plant area when the concentration of vinyl chloride in that area exceeds the limit set forth in paragraph (b).

2/ This paragraph in the proposed standard should be lettered "(d)"; it is shown as "(e)" in the "Recommended changes" because of the recommended inclusion of a new paragraph (b).

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| I | II | III |
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| (3) Employees or their designated representatives shall be afforded an opportunity to observe monitoring and measuring required by this paragraph.<br>(i) Where exercise of an opportunity requires [illegible] where the use of protective clothing equipment [illegible]<br>(ii) Before exercising the opportunity [illegible]<br>(A) the [illegible] and the record of [illegible]<br>(B) The protective steps and measures [illegible]<br>(iii) Observers shall be permitted without interference to [illegible]<br>(A) Observe all steps and procedures [illegible]<br>(B) Record quantities and results [illegible]<br>(C) Observe the condition of monitoring [illegible]<br>(D) Receive a copy of the [illegible]<br>(E) Examine instructions and documents [illegible] | (f)(2)(iv) The monitoring equipment shall produce an audible and visible alarm, readily distinguishable from that required by (f)(2)(iii), in any plant area when the concentration of vinyl chloride in that area exceeds 100 ppm.<br><br>(f)(3)...elected...a reasonable opportunity...<br><br>(f)(3)(i) through (f)(3)(iii) - [Delete]<br>Replace by:<br><br>(f)(3)(i) Summaries of monitoring results including the daily maximum and average for each probe location shall be kept available. Employees or their elected representatives shall have reasonable opportunities to inspect the raw data from which the summaries have been prepared. | It is anticipated that the constant sequential monitoring envisioned here will result in instrument charts and/or computer print-outs. The only meaningful information generated would be the summaries referred to in the "recommended change". Since the probes will be in fixed locations, "observation" here would have no practical significance and the details set forth in the proposed standard have no applicability. |
| (4) Accurate and complete records of all required monitoring shall be made and maintained for not less than 20 years. Such a record shall (i) state the date of such monitoring and the levels determined; and (ii) identify the instruments and methods used. | (f)(4)...30... | |

I

(f) Engineering controls and work-
practice methods. (1) Where protection
[illegible]
methods and respirators as follows:

(i) Feasible engineering controls and workpractice methods shall immediately be used to reduce airborne concentrations of vinyl chloride below the detectable level;

(ii) Wherever feasible engineering controls and workpractice methods which can be instituted immediately are not sufficient to reduce concentrations of vinyl chloride below the detectable level, they shall nonetheless be used to reduce the concentrations to the lowest practicable level, and shall be supplemented by means of respirators in accordance with paragraph (g) of this section;

(iii) Wherever no feasible engineering control or workpractice method can be instituted immediately, immediate respiratory protection shall be provided in accordance with paragraph (g) of this section; and

(iv) In any case covered by paragraph (f)(1) (ii) or (iii) of this section, the employer shall also undertake as soon as practicable a program to reduce airborne concentrations of vinyl chloride below the detectable level, or to the greatest extent feasible, solely by means of engineering controls and workpractice methods and as soon as feasible.

II.

(g)(1) ...levels of vinyl chloride in excess of the limits set forth in paragraph (b),...

(g)(1)(i)...[Same as (g)(1)]

(g)(1)(ii)...[Same as (g)(1)]...h...

(g)(1)iv)...the limits set forth in paragraph (b),...

I

(g) *Respiratory protection.* (1) A respiratory protection program in accordance with § 1910.134 shall be established and implemented where respirators are required to be used by this section.

(2) Respirators shall be used only in cases of emergency and where required by any other provision of this section. Respirators may not be used in lieu of feasible engineering controls or work-practice methods.

(3) Respirators or combinations of respirators for protection against vinyl chloride shall be selected from among the following:

(i) A positive pressure full facepiece self-contained breathing apparatus;

(ii) A pressure-demand full facepiece self-contained breathing apparatus operating in the pressure-demand mode;

(iii) A combination type "C" pressure-demand full facepiece respirator operating in the pressure-demand mode and a pressure-demand self-contained breathing apparatus operating in the pressure-demand mode; or

(iv) A combination type "C" continuous flow respirator and a pressure-demand self-contained breathing apparatus operating in the pressure-demand mode. [add]

II

(h)(3)(i)...self-contained or air supplied breathing apparatus.

(h)(3)(ii)...self-contained or air supplied breathing apparatus.

(h)(3)(iii) [Delete]

Add the following new paragraph:

(h)(3)(v) A half-face, canister-type mask when the concentration of vinyl chloride is above the limit set forth in paragraph (b) but below 100 ppm.

Until a suitable indicator system has been developed to show when the canister is no longer effective, each regulated area shall develop a work-practice rule that provides for the replacement of used canisters when such canisters have consumed 50% of specified capacity but no less than daily replacement when such canisters have been used at all.

III

| I | II | III |
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| (h) *Protective clothing.* (1) Employees entering regulated areas shall be provided [illegible] protective clothing [illegible] and gloves at no cost to them [illegible] to wear while in the regulated area. | (i)(1) This item should be deleted. | Under general working circumstances special protective clothing is neither available nor necessary. |
| (2) Where polyvinyl chloride powder containing detectable levels of vinyl chloride is handled, employees shall also be: | (i)(2)...levels of vinyl chloride in excess of the limit set forth in paragraph (a)... [delete "also"] | |
| (i) Provided and required to wear headcoverings; | | |
| (ii) Required to remove all protective clothing at each exit from the regulated area; and | (i)(2)(ii)...excess polyvinyl chloride powder from clothing by vacuuming or brushing... | |
| (iii) Required to shower after the last exit of the day. | (i)(2)(iii) [Delete] | We see no useful purpose being served by this requirement. |
| (3) Clean protective clothing shall be provided whenever contaminated or soiled, but not less frequently than weekly. Contaminated clothing shall be decontaminated before reuse by removal for laundering or disposal. | (i)(3)...headcoverings... | |
| (i) *Hygiene facilities and practices.* (1) Where employees are required by this section to wear protective clothing and equipment, change rooms shall be provided in accordance with § 1910.141(e). | ...headcoverings... | |
| (2) Where employees are required by this section to shower, shower facilities shall be provided in accordance with § 1910.141(d)(3). | | |
| (3) Storage or consumption of food or beverages, storage or use of smoking or tobacco products, and the [illegible] application of cosmetics are prohibited in regulated areas. | (j)(3) Storage or consumption of smoking products are prohibited in regulated areas. | We see no reason why chewing gum or the use of cosmetics should be barred. |

(j) Emergency situations. (1) A written operational plan for emergency situations shall be developed for each regulated area.

(2) In the event of an emergency, appropriate portions of the plan shall be put into operation.

(i) Hazardous conditions created by the emergency shall be eliminated and the affected area shall be decontaminated prior to the resumption of normal operations.

(ii) Special medical surveillance by a physician shall be instituted within 24-hours for employees present in the affected area at the time of the emergency.

(iii) Where an employee has a known contact with liquid vinyl chloride such employee shall be required to shower as soon as possible, unless contraindicated by physical injuries.

(iv) An incident report on the emergency shall be reported as required in paragraph (q)(2) of this section.

(3) Each authorized employee shall be trained in a program relating to the hazards of vinyl chloride and the precautions for safe use.

(i) The program shall include:

(A) The nature of the fire hazard, and the necessary protective steps;

(B) The nature of the toxic hazard including local and systemic effects, acute and chronic effects including specifically the carcinogenic hazard;

(C) The specific nature of operations which could result in exposure to vinyl chloride, and necessary protective steps;

(D) The purpose for and application of the medical surveillance program;

(E) The purpose for and application of decontamination practices;

(F) The purpose for and significance of emergency practices and procedures;

(G) The employee's specific role under normal operating or emergency conditions;

(H) Specific information to aid the employee in recognition and evaluation of conditions and situations which may result in the release of vinyl chloride;

(I) The purpose for and application of specific first aid procedures and practices;

(J) A review of this standard at the employee's first training and indoctrination program and annually thereafter.

(ii) All materials relating to the program shall be provided upon request to authorized representatives of the Assistant Secretary and the Director.

(k)(2)(iii)...an amount sufficient to create an emergency...

(k)(3) [This paragraph relates to a desirable general training program, not to emergencies. We recommend that it be placed in a separate lettered paragraph.]

(k) *Signs and labels.* (1) Entrances to regulated areas shall be posted with signs bearing the legend:

CANCER-SUSPECT AGENT AREA

3/ (2) Areas containing operations covered in paragraph (k)(1)(4) of this section shall be posted with signs bearing the legend:

CANCER-SUSPECT AGENT IN THIS AREA
WHERE RESPIRATORY AIR-[illegible] EQUIPMENT REQUIRED
AUTHORIZED PERSONNEL ONLY

(3) Containers of waste or other materials contaminated with vinyl chloride shall be labeled:

VINYL CHLORIDE CONTAMINATED
CANCER-SUSPECT AGENT
DISPOSE OF OR DECONTAMINATE USING [illegible]
AUTHORIZED PROCEDURES

(1)(1)...:

VINYL CHLORIDE VAPOR HAZARD
USE ASSIGNED PROTECTIVE EQUIPMENT WHEN ALARM
SIGNAL IS ACTIVATED
WHEN SIGNAL IS ACTIVATED, DO NOT REMAIN IN ALARM AREA
UNLESS YOUR WORK REQUIRES IT
BREATHING EXCESSIVE QUANTITIES OF VINYL CHLORIDE VAPOR
MAY BE HAZARDOUS TO YOUR HEALTH
AUTHORIZED PERSONNEL ONLY

(1)(2)...:

VINYL CHLORIDE VAPOR IN THIS AREA
PROTECTIVE CLOTHING AND
RESPIRATORS REQUIRED
AUTHORIZED PERSONNEL ONLY

(1)(3)...:

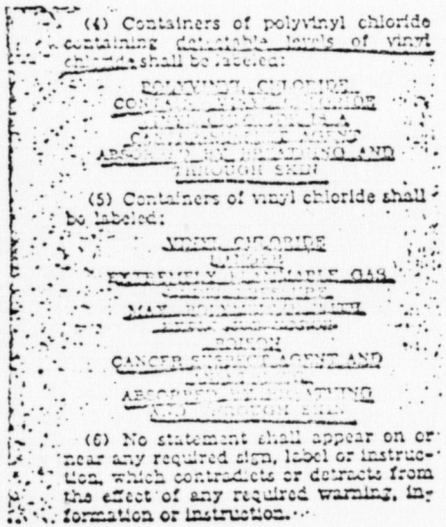
VINYL CHLORIDE CONTAMINATED MATERIAL
MAY BE HAZARDOUS TO YOUR HEALTH
DISPOSE OF OR DECONTAMINATE USING ADEQUATE
VENTILATION OR PROTECTIVE EQUIPMENT

3/ It is assumed that the paragraph (k)(1)(4) to which reference is made in this paragraph should read paragraph (1)(4).

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(1)(4)...levels of vinyl chloride in excess of the limits set forth in paragraph (a)...:

POLYVINYL CHLORIDE
CAUTION
CONTAINS VINYL CHLORIDE
AVOID BREATHING VAPOR OR DUST
CLOSED CONTAINERS OF POLYVINYL CHLORIDE MAY CONTAIN
VAPOR LEVELS OF VINYL CHLORIDE WHICH MAY
BE HAZARDOUS TO YOUR HEALTH
OPEN ONLY IN WELL-VENTILATED AREAS OR WEAR RESPIRATORY
PROTECTION



(4) Containers of polyvinyl chloride containing detectable levels of vinyl chloride shall be labeled:

POLYVINYL CHLORIDE
CONTAINS VINYL CHLORIDE
AVOID BREATHING VAPOR AND
THROUGH SKIN

(5) Containers of vinyl chloride shall be labeled:

VINYL CHLORIDE
EXTREMELY FLAMMABLE GAS
MAY
POISON
CANCER
AVOID BREATHING

(6) No statement shall appear on or near any required sign, label or instruction, which contradicts or detracts from the effect of any required warning, information or instruction...

(1)(5)...:

VINYL CHLORIDE
DANGER
EXTREMELY FLAMMABLE GAS UNDER PRESSURE
MAY POLYMERIZE WITH EXPLOSIVE FORCE
AVOID CONTACT WITH LIQUID OR VAPOR UNLESS FULLY
PROTECTED BY AUTHORIZED EQUIPMENT
IN THE EVENT OF ACUTE EXPOSURE SEEK MEDICAL
ASSISTANCE IMMEDIATELY

Vinyl chloride is not a poison as defined by other governmental regulations.

(1) *Maintenance and decontamination.* (1) Emphasis shall be placed upon immediate clean up of spills, periodic inspection, prompt repair of equipment and leaks, and proper handling, storage and disposal or decontamination of materials to prevent airborne contamination and accidental skin contact with vinyl chloride. Waste materials, equipment, and other sources of vinyl chloride in closed containers, may not be placed in areas of excessive temperature or sunlight since build-up of internal pressure may result in rupture of the container, fire or explosion.

(2) Waste resins or other materials contaminated with vinyl chloride shall be placed in closed containers pending disposal or decontamination.

(3) Appropriate procedures shall be developed and implemented for the decontamination or disposal of all such waste material.

(4) In maintenance or repair operations on contaminated systems or equipment, including vessel entry, employees engaged in such operations shall be (i) provided with and required to wear and use a whole-body air-supplied suit impervious to vinyl chloride, and a [illegible] in accordance with paragraph (g) of this section, and (ii) required to shower after removing protective equipment.

(m)(4)(i)...protective clothing, a respirator in accordance with paragraph (h) of this section, gloves, and protective footwear.

Use of an air-supplied whole body impervious suit constitutes a major health and safety hazard. The recommended change permits an employee to be protected where he:

(1) uses prescription glasses,
(2) is in a vessel with a safety harness to permit his removal in case of accident,
(3) needs to wear a hard hat.

(m)(4)(ii) [Delete]

Since no contact with vinyl chloride will occur, this provision is unnecessary.

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| (5) Protective clothing and equipment shall be clean and dry for each use.<br>(6) When vessels or piping systems are opened local exhaust ventilation shall be provided to remove the escaping vapor from all occupied areas.<br>(7) (i) Vessels to be entered shall first be ventilated and monitored so that the concentration of vinyl chloride is reduced to a level within the protection factor capability of the protective equipment.<br>(ii) When vessels are to be entered, all piping to such vessel shall be:<br>(A) Opened, blanked and tagged; or<br>(B) Where welded piping is in use, not less than 2 valves in series, which isolate the vessel from any other connection to such line, must be closed and secured.<br>(iii) No employee shall enter a vessel, except when another employee properly trained and equipped for entry is present and is observing the employee in the vessel. The observer shall have means for signalling for help in the event the employee experiences problems. Under such conditions, the observer shall signal for help, and shall not enter to assist the employee until another person is present to observe.<br>(m) *Transportation loading and unloading.* (1) Facilities for the loading and unloading of vinyl chloride to and from containers shall have each transfer line and vapor-equalizing line equipped with vent connections, and shall have an inert gas purging system. Vent and purge effluent shall be returned to a process stream or flared in a safe location.<br>(2) Procedures shall be developed and implemented for the transfer of vinyl chloride. Written copies of such procedures shall be provided employees engaged in such operations, and such employees shall be fully trained and rehearsed in all procedures.<br>(3) Employees engaged in transfer operations shall be provided with and required to wear respirators in accordance with paragraph (g) of this section.<br>(n) *Polymer handling operations.* (1) Containers of polyvinyl chloride releasing detectable levels of vinyl chloride shall be opened and transferred only under local exhaust ventilation which reduces the concentration of vinyl chloride below the detectable level.<br>(2) Wet operations, such as but not limited to slurry, calendering and extrusion, where release of vinyl chloride [illegible] shall be carried on only under local exhaust ventilation which reduces the concentration of vinyl chloride below the detectable level. | (m)(7)(ii)(B) [Delete] | Alternate B should be permitted for all piping. |
| | (m)(7)(iii) Insert the following:<br>..., or a mechanical standby is provided which requires acknowledgement from the man inside the vessel on a 2 1/2 minute time cycle and another man (observer) is in the area to assist the man in the vessel if he does not respond. | |
| | (n)(1) [Delete] | An inert gas purge is neither necessary nor always practicable. Purging back to the process is feasible and provides equivalent protection. |
| | (o)(1)...levels of vinyl chloride above the limits set forth in paragraph (a)... [Delete] | |
| | (o)(2) [Delete] | Testimony to be presented shows that fabricating and processing plants pose no problems and should be excluded from coverage of the proposed standard. |

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| (o) *Medical surveillance.* Not later than ---------- 1974, a program of medical surveillance shall be instituted, and shall provide each authorized employee with an opportunity for examinations in accordance with this paragraph. All medical examinations and procedures shall be performed by or under the supervision of a licensed Doctor of Medicine (MD) or Doctor of Osteopathy (DO). All medical examinations and tests shall be provided without cost to the employee. | | |
| (1) At the time of initial employment, or upon institution of screening, a physical examination shall be performed with specific attention to detecting enlargement of the liver or disorders of liver function. | (p)(1) [Delete] | It is the concensus of medical opinion that there are no diagnostic or screening procedures that will detect sensitivity or predisposition to angiosarcoma of the liver. Consequently a standard should not specify what tests should be performed, but should leave medical examinations to the discretion of the examining physician. |
| (2) At the time of initial employment or upon institution of screening, and annually thereafter, a medical history checklist shall be completed by the employee. This list shall include questions concerning: | (p)(2) [Delete] | |
| (i) Alcohol intake; | | |
| (ii) Past history of hepatitis; | | |
| (iii) Past exposure to potential hepatotoxic agents including drugs and chemicals; | | |
| (iv) Past history of blood transfusions; and | | |
| (v) Past history of hospitalizations. | | |
| (3) At the time of initial employment, or upon institution of screening, a serum specimen shall be obtained for screening with respect to the following biochemical determinations of liver function: | (p)(3)...suitable samples shall be taken to permit the performance of all tests deemed necessary by the examining physician. | |
| (i) Total bilirubin; | | |
| (ii) Alkaline phosphatase; | | |
| (iii) Serum glutamic oxaloacetic transaminase (SGOT); | | |
| (iv) Serum glutamic pyruvic transaminase (SGPT); and | | |
| (v) Gamma glutamyl transpeptidase (GGTP). | | |
| (4) Additional tests that may optionally be conducted for use in screening include: | (p)(4) [Delete] | |
| (i) Lactic dehydrogenase; | | |
| (ii) Lactic acid determinations; | | |
| (iii) Serum protein electrophoresis; and | | |
| (iv) Platelet count. | | |

| I | II | III |
|---|---|---|
| (5) Laboratory analyses for all biological specimens included in medical examinations shall be performed in laboratories accredited by the College of American Pathologists or licensed under 42 CFR Part 74. | | |
| (6) If the results of screening required in paragraph (o)(2) of this section are normal, screening shall be repeated: (i) Every six months for employees who have been employed in vinyl chloride related operations for 10 years or more; and (ii) Annually for all other employees entering regulated areas. | | |
| (7) If one or more liver function tests [illegible] | (p)(7) [Delete] | Decisions as to the significance of tests, and recommended procedures should be made by the physician. |
| (8) If [illegible] | (p)(8) [Delete] | |
| (9) A complete and accurate record of the results of medical examinations shall be made and maintained for the duration of employment plus five years, or for 20 years, whichever is longer. (p) Records. (1) Records of monitoring and measuring, medical records, and regulated area entry rosters and summaries, shall be made available for examination and copying upon request to authorized representatives of the Assistant Secretary and the Director. | | |

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(2) In the event that the employer ceases to do business and there is no successor to receive and retain his records for the prescribed period, these records shall be transmitted by registered mail to the Director, and each employee individually notified in writing of this transfer.

(3) Employees and their designated representatives shall be provided access to examine and copy records of monitoring and measuring.

(4) Former employees shall be provided access to examine and copy records reflecting their own exposures.

(5) Upon written request of any employee, a copy of the medical record of such employee shall be furnished to a physician designated by the employee in such request.

(g) *Reports.* (1) Not later than ------ the following information shall be reported to the OSHA Area Director. Any change in such information shall be reported to the OSHA Area Director within 15 days of such change.

(i) The address and location of each establishment which has one or more regulated areas; and

(ii) The number of employees in each regulated area during normal operations, including maintenance.

(2) Incidents which result in the release of toxic materials into any area where employees may be present shall be reported in accordance with this paragraph.

(i) A report of the occurrence of the incident and the facts obtainable at that time including a report on any medical treatment of affected employees shall be made within 24 hours to the OSHA Area Director.

(ii) A written report shall be filed with the OSHA Area Director within 15 calendar days thereafter and shall include:

(A) A specification of the amount of material released;

(B) A description of the area involved and the extent of known and potential employee exposure and area affected;

(C) A report on any medical treatment of affected employees and any medical surveillance program implemented; and

(D) An analysis of the circumstances of the incident and measures taken or to be taken, with specific completion dates, to avoid further similar releases.

(g)(3)...reasonable access...

(g)(4)...reasonable access...

(r)(2)(i)...emergency...

(r)(2)(ii)(B)...emergency...

I

(3) Upon completion of any monitoring and measuring which discloses that any employee has actually been exposed to detectable levels of vinyl chloride, each such employee shall be individually notified in writing. The notice shall:

(i) Be delivered not later than 10 working days after the completion of the monitoring and measuring;

(ii) State the actual exposure in terms of concentration and time; and

(iii) State the steps which have been taken and will be taken with respect to the employee's exposure to bring the employee's exposure in compliance with [illegible]

II

(r)(3)...levels of vinyl chloride in excess of the limits set forth in paragraph (b)...The employee shall:

(r)(3)(i) [Delete, and replace by the following]:

Be notified of the exposure as soon as practicable, but not later than five working days after the finding; and,

(r)(3)(ii) Be informed of...

(r)(3)(iii) [Delete, and replace by the following]:

Be notified in a timely fashion of the corrective action being taken.

III

(Secs. 6(b), 6(c), and 8(c), 84 Stat. 1593, 1598, 1599 (29 U.S.C. 655, 657); Secretary of Labor's Order No. 12-71 (36 FR 8754))

Signed at Washington, D.C. this 6th day of May, 1974.

JOHN STENDER,
*Assistant Secretary of Labor.*

[FR Doc.74-10748 Filed 5-9-74;8:45 am]

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